D.D.N.J., F.D.C. 7881–7940 Issued January 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7881–7940

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, including, in one case, the entry of a consent decree of permanent injunction, and in which, in one case, a decree of dismissal was entered upon motion of the claimant; and (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

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GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *January 15, 1965.*

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*For presence of a habit-forming substance without warning statement, see Nos. 7883, 7888; drug actionable because of contamination with filth, No. 7888; omission of, or unsatisfactory, ingredients statements, Nos. 7883, 7888, 7892, 7935, 7936; an imitation of, and sale under name of, another drug, Nos. 7920, 7921; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7883, 7888, 7892; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7883, 7888, 7892, 7914; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 7888, cosmetics actionable under the drug provisions of the Act, Nos. 7935, 7936.

757–345—65——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7881–7940

Adulteration, Section 501(a)(1) the article consisted in whole or in part of a decomposed substance; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its purity or quality fell below, that which it purported or was represented to possess; Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man, and it contained a quantity of the narcotic or hypnotic substance, peyote, or of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein: Section 502(e)(1)(A), the article was a drug, and its label failed to bear, (i) the established name of the drug, and (ii), in the case where the article was fabricated from two or more ingredients, the established name and quantity of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, bacitracin, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

7881. Enema device, heat-therapy device, and Hemovitameter device. (F.D.C. No. 49932. S. Nos. 58–630 X, 62–062/3 A.)

QUANTITY: 2 *enema devices*, 1 *heat-therapy device*, and 1 *Hemovitameter device* with accessory unit, at Los Angeles, Calif., in possession of Ace Medical Instrument Co.

SHIPPED: On unknown dates, from outside the State of California.

ACCOMPANYING LABELING: An untitled 53-page booklet pertaining to the *heat-therapy device*, and a booklet entitled "Gordon Detoxifier Diagrams and Instruction For Instrument No. 842" pertaining to the *enema device*.

RESULTS OF INVESTIGATION: Examination indicated that the *enema device* consisted of a maze of valves, knobs, tubing, water and air pipes and various other plumbing fixtures to provide water of various temperatures through an applicator placed in the rectum for the purpose of flushing out fecal and other intestinal accumulations; a wall-mounted panel contained the plumbing fixtures, a timer, and thermometer.

The *heat-therapy device* consisted of a wooden cabinet with a front-operating panel containing a timer, an ammeter, and a heat-control resistor and a control switch, together with a large heating "applicator" pad which in operation was applied to the patient's body.

The *Hemovitameter device* consisted of: (1) a large wood console housing a radionic-type electrical device with a large central instrument panel containing several dozen switches, dials, meters, rheostats, and electrode connectors as well as two smaller side panels and a drawer-type detector plate; and (2) an accessory unit known as "Hemovitameter Elementary Food Chart," which was in a large wooden cabinet with a lighted front panel bearing the names of elements, chemical compounds, food tablets and dietary recommendations; in use, electrodes from the device were attached to the patient while the practitioner-operator sat or stood in front and manipulated the dials and switches; and, after purportedly locating the site of the disease and its identity, the operator employed the accessory unit to determine what remedial elements or dietary needs were required to effect a cure.

LIBELED: 3–19–64, S. Dist. Calif.

CHARGE: *Enema device*, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for re-establishing normal tone of the bowel, constipation, healing intestinal ulcerations, restoration of normal peristalsis, lessening rheumatic pains, ulcerated colon, prostatic trouble, appendicitis, ulcerative colitis, ulcers of the stomach and bowels, irritated or ulcerated surfaces, high blood pressure, low blood pressure, atonic and spastic conditions, roundworms in the intestines, asthma and rheumatic cases, skin eruptions, and toxic hearts; 502(j)—the article was dangerous to health when used with the frequency, and duration prescribed, recommended, and suggested in its labeling; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended.

Heat-therapy device, 502(a)—the 53-page untitled booklet accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for pneumonia, asthma, bronchitis,

hypertension, anemia, arthritis, gout, neuritis, edema, Buerger's disease, varicose veins, phlebitis, dementia praecox, albuminuria, and Parkinson's disease; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended.

Hemovitameter device, 502(a)—(1) statements and designations appearing on the front panel of the Hemovitameter console device, namely: Diagnosis Lamp–Diagnosis–Treating Intensity–Treatment Volume Controls–Treating A–Treating B–Intensity Increase–Nerve Energy–low-med–Identification–Vita Meter–Age In Years–General Visceral–Treating Electrodes–Viscerals–General Treat.–Visceral Treat.–Treating Bank–Blood Test–Food Test–Nerve energy–and, (2) statements and designations appearing on the lighted dial of the Hemovitameter Elementary Food Chart, namely, Elements–Chemical Compounds–Food Tablets Recommended–Functions–Source Foods–Positive–Dietary–Blood Builder Compound With Iron–Builds Tissue Nerve Cells– Governs Cell Life Nerves–Normal Growth Tissue–Respiration–Hair Nails Skin–Circulation Muscle Function–Retarded Growth–Skin Conditions–Cell Life Bone Teeth–Nerve Relaxation–Laxative Effect–Blood Cell Development–Thyroid Gland Brain Nerves–Bone Teeth Muscle Functions–Iron Balance in Tissue–Digestion–Hair Teeth Eyes Nails–Regulates Body Temperature–Cell Life–Digestion Blood Tissue, were false and misleading in that they represented and suggested that the article was adequate and effective for treating or diagnosing diseases and for testing to determine dietary requirements for diseases or abnormal body conditions, whereas the article was not adequate and effective for any diagnostic, testing, or treatment purpose; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes and conditions for which it was intended.

DISPOSITION: 4–13–64. Default—delivered to the Food and Drug Administration.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

7882. Vasodilators. (F.D.C. No. 49468. S. Nos. 54–915/18 X.)

QUANTITY: 40 cases, each containing 12 1-pt. btls. of *Feverill*, 44 cases, each containing 12 100-tablet btls. of *Shertrate-B*, and 48 cases, each containing 12 100-tablet btls. of *Shertrate*, at Louisville, Ky.

SHIPPED: Between 6–26–62 and 3–11–63, from St. Louis, Mo., by E. W. Heun Co., and Norwood Laboratories, Inc.

LABEL IN PART: (Btl.) "Feverill Each cc * * * Contains Methampyrone Sodium 500 mg. Chlorpheniramine Maleate 0.5 mg. [or "Shertrate-B Prolonged Action Vasodilator, Sedative Each Prolonged Action Press-Coated Tablet Contains: Pentaerythrityl Tetranitrate 45 mg. Butabarbital * * * 50 mg." or "Shertrate Prolonged Action Coronary Vasodilator, Sedative Each Prolonged Action Press-Coated Tablet Contains: Pentaerythrityl Tetranitrate 45 mg."] Manufactured for Sheryl Pharmaceuticals, Inc., Louisville, Kentucky."

RESULTS OF INVESTIGATION: Analysis showed that the *Feverill* contained 101.9 percent (some bottles) and 88.0 percent (some bottles) of the declared amount of methampyrone sodium; and *Shertrate-B tablets*, approximately 40.7 mg. and *Shertrate tablets*, approximately 43.4 mg. of pentaerythrityl tetranitrate per tablet.

LIBELED: 10–15–63, W. Dist. Ky.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to each such drug.

DISPOSITION: On 12–12–63, Sheryl Pharmaceuticals, Inc., Louisville, Ky., filed an intervening libel in regard to the *Shertrate* and *Shertrate-B*. On 1–13–64, the Government moved to strike the intervening libel and the intervening libellant served interrogatories on the Government, which were answered by the Government. On 2–17–64, the court entered an order dismissing the intervening libel, and, on 3–11–64, a default decree of condemnation ordering destruction of the articles was entered.

7883. Mescaline sulfate powder and powdered peyote. (F.D.C. No. 49641. S. Nos. 21–438/9 X, 23–246 X.)

QUANTITY: 1 btl. containing 6½ gms. of *mescaline sulfate powder*, and 20 200-mg., 15 400-mg. and 5 300-mg. unlabeled capsules of *mescaline sulfate;* and 1 plastic bag containing 217 gms. of *powdered peyote*, at Socorro, N. Mex., in possession of Socorro Clinic and/or John W. Aiken, D.O.

SHIPPED: 9–21–63, from Colnbrook, England, by L. Light Co., Ltd.; and May 1963, from San Antonio, Tex.

LABEL IN PART: (Btl.) "L. Light & Co., Ltd. Colnbrook, England Mescalin Sulfate To be used by qualified investigators only Batch No. 19 20 grams For Lab Use Only."

RESULTS OF INVESTIGATION: The *powdered peyote* in the plastic bag had been shipped in button form from Texas and had been ground into the powder by John W. Aiken. The *mescaline sulfate capsules* had been encapsulated from the contents of the bottle. Analysis showed that all the articles contained mescaline.

LIBELED: 12–16–63, Dist. N. Mex.; libel amended 1–10–64.

CHARGE: *Mescaline sulfate powder*, 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug and it was not exempt since it did not comply with the regulations regarding new drugs for investigational use.

Peyote powder, 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(d)—the label failed to bear the name and quantity or proportion of the hypnotic substance, namely, peyote, and, in juxtaposition therewith, the statement "Warning—May be habit-forming"; 502(e)(1)(A)(i)—the article failed to bear a label containing the established name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2–25–64. Default—destruction.

7884. Various prescription drugs. (F.D.C. No. 46074. S. Nos. 46–563/7 R, 48–199/200 R.)

QUANTITY: Approximately 2,000 lbs., at Cleveland, Ohio, in possession of Ohio First Aid & Pharmacal Co., Inc.

SHIPPED: On unknown dates, from outside the State of Ohio, by various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into bottles having labels bearing brand names indicative of manufacture outside the State of Ohio, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the words "Physician's Sample," "Complimentary Not to be Sold," or similar wording, and the names and addresses of manufacturers, packers, or distributors outside the State of Ohio.

LIBELED: 7–12–61, N. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the statements "Complimentary," "Patient Starter Package," "Physician's Sample," "Complimentary Not to be Sold," "Sample Not to be Sold," and similar wording borne on the labels of said articles, were false and misleading as applied to those articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot number as required by the regulations; 502(l)—one of the articles was a drug composed of a derivative of chlortetracycline and it was not from a batch with respect to which a certificate or release was effective pursuant to 507 since it was in a repackaged condition and had not been certified since repacking; and 505(a)—the repacked articles, labeled in part "Naturetin," "Librium," "Kynex," and "Aristogesic," were new drugs which may not be introduced or delivered for introduction into interstate commerce under the provisions of 505(a) since applications filed pursuant to 505(b) were not effective with respect to such drugs.

DISPOSITION: 2–26–63. Default—destruction.

7885. Byvirol syrup and nandrolone phenpropionate injection. (F.D.C. No. 49243. S. Nos. 65–823 V, 65–833 V.)

QUANTITY: 1,800 individually ctnd. 4-oz. btls., and 300 individually ctnd. 1-oz. btls., 27 unlabeled 32-oz. btls., 55 unlabeled 16-oz. btls., 2,256 unlabeled 4-oz. btls., and 1,165 unlabeled 1-oz. btls. of *Byvirol syrup;* and 891 unlabeled 2-cc. vials and 205 unlabeled 10-cc. vials of *nandrolone phenpropionate injection*, at Parsippany-Troy Hills, N.J.

SHIPPED: Between 9–20–62 and 9–29–62, from New York, N.Y., by Pure Laboratories, Inc.

LABEL IN PART: (Btl.) "Byvirol Syrup * * * Pure Laboratories, Inc. New York, N.Y., Distr. Each 5 cc. (1 teaspoonful) contains: Vitamin B–1 10 mg. * * * Vitamin B–12 25 mcg. (Activity Concentrate) Dosage."

ACCOMPANYING LABELING: Carton insert entitled "Byvirol A New Scientifically Compounded Vitamin Tonic For Children Who Just Won't Eat!"; display cartons reading in part "A High Potency * * * Vitamin B–12 B–1 Tonic * * *"; leaflet entitled "Byvirol Grow Chart"; and extra bottle labels.

LIBELED: 8–30–63, Dist. N.J.

CHARGE: *Byvirol syrup*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective to stimulate appetite, promote growth, and to enable one to grow big and strong.

Nandrolone phenpropionate injection, 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 12–10–63. Consent—claimed by Pure Laboratories, Inc., for the purpose of destroying the *nandrolone phenpropionate injection* and relabeling the *Byvirol syrup*.

DRUGS FOR VETERINARY USE

7886. Unistat. (F.D.C. No. 47202. S. No. 431 T.)

QUANTITY: 40 50-lb. bags at Dalton, Ga.

SHIPPED: Prior to 2–8–62, from Charles City, Iowa, by Dr. Salsbury's Laboratories.

LABEL IN PART: (Bag) "Dr. Salsbury's Unistat * * * Active Ingredients: 3,5-Dinitrobenzamide 25% Acetyl-(para-Nitrophenyl)-sulfanilamide 30% 3-Nitro-4-hydroxyphenlarsonic acid 5% * * * Dr. Salsbury Laboratories, Charles City, Iowa."

LIBELED: 3–6–62, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use of the article in final dosage form and it was not exempt from such requirement, since there was no effective new drug application for the final dosage form, namely, "Strain's Broiler Mash Medicated" in which the article was to be incorporated; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no new drug application filed pursuant to law was effective with respect to such drug when shipped, as in this case, to a feed manufacturer who held no effective application for the use of such drug in animal feeds.

DISPOSITION: Georgia Poultry Feed Mills, Inc., Dalton, Ga., appeared as claimant and filed an answer, on 4–13–62, denying the misbranding and new drug charges in the libel. Thereafter, the claimant served written interrogatories upon the Government, which were answered. A motion to compel further answers to interrogatories was subsequently served by the claimant upon the Government. Interrogatories were also served by the Government upon the claimant, which were answered in part and objected to in part. On 4–22–63, after consideration of the briefs and arguments of counsel, the court handed down the following opinion on the objections to interrogatories:

HOOPER, *District Judge:*

ORDER ON OBJECTIONS TO INTERROGATORIES

"Interrogatories have been filed by both the Government and the claimant and objections thereto bring into play the merits of the case. The United States has seized 50 pounds of 'Unistat' in possession of the claimant, Georgia Poultry Feed Mills, Inc. of Dalton, Georgia, alleging in its brief 'that the Unistat was violative of the Act (21 U.S.C.A., § 301, et seq.) when shipped because it was shipped to a feed manufacturer for incorporation in a medicated feed who did not possess the required application.'

"Interrogatories No. 7 and No. 8 propounded by the Government 'relate to the use or uses which were to be made of the seized drug "Unistat".'

"Stipulation of Facts filed April 12, 1962 show that the article seized was manufactured by Dr. Salsbury's Laboratories, Inc. of Charles City, Iowa, and shipped to a branch of said company in Georgia, and then shipped to claimant at Dalton. Unistat is a new drug within the meaning of 21 U.S.C., § 321(p) subject to the requirements of 21 U.S.C., § 355 as in force on the date this action was commenced (it was shipped prior to February 8, 1962 and the amendments to the Act referred to were made October 10, 1962).

"It is stipulated that said laboratories filed new drug application No. 11,141, that it was made effective on December 19, 1957 and was in effect at all pertinent times herein; that it contains data which demonstrates the safety of Unistat when used in accordance with the labeling, etc. The labeling on the drug seized is identical to that contained in the application and the directions are not criticized by the Government. When seized the drug was in its original unopened packages.

"The libel does not allege that the claimant had received in commerce the drug in question with the intent and purpose to use it in the preparation of feed to be illegally shipped in commerce, nor does the libel charge that the laboratories in shipping the same knew of any such contemplated illegal use. As stated above, the libel complains that the application filed by the manufacturer 'is not effective with respect to such drug when shipped as here to a feed manufacturer who holds no effective application for its use in animal feeds.' It is alleged that the product was 'misbranded when introduced into and while in interstate commerce' and that 'the labeling fails to bear adequate directions for use of the drug *in final dosage form*,' and there was no 'effective application for final dosage form, namely Strain's Broiler Mash Medicated' (the name under which the feed was sold by claimant, see Paragraph 4).

"A careful reading of the statutes in question as well as Minutes of the FDA Conference on said statute and the proposed regulations, held February 15, 1963, convinces this Court that the manufacturer of Unistat did not violate the statute in question in shipping said product into this state. The statute in question contains penalties by way of seizure and forfeiture and also criminal penalties. It is not disputed that Unistat is a new drug as defined in 21 U.S.C., § 321(p), but neither is it disputed that it was labeled in accordance with the application when shipped into this state, and there is no violation of 21 U.S.C., § 352(f)(1).

"There are no provisions in the statute nor in said application which restricted Dr. Salsbury's Laboratories from shipping Unistat to feed dealers in other states. If such dealers have the intention to use Unistat in the manufacture of animal feed in a way that violates said statutes, the appropriate action would seem to be against such dealer, but in the instant case the gravamen of the Government's complaint is that the Laboratories 'shipped in interstate commerce prior to February 8, 1962 the said Unistat and that such shipment was illegal because it was made to a feed manufacturer who holds no effective application for its use in animal feeds.'

"Nothing contained in the Minutes of the Conference of February 15, 1963 indicates that the statute is applicable to the facts of the instant case. In only one instance was very much said about the use of the drug supplement by retail feed dealers by mixing with grain products. There is the following colloquy:

> *Mr. Harvey:* Is an NDA supplemental application required from the retail feed dealer who mixes the drug supplement with the grain products?
>
> *Dr. Durbin:* That would depend on the labeling under which the feed dealer gets the drug product. If he is not a holder of a supplemental new drug application and he receives a product that he could not market without further mixing, then he may need a supplemental application. If he gets a product that the farmer himself could buy and reduces it in strength to sell, he wouldn't need any supplemental application. I might add, that most new drug applications carry a commitment to sell only to holders of new drug applications, or holders of supplements. This question applied to a new drug would be answered by the type of new drug application available.

"It should be noted that a doubt is cast upon the question as to whether such retail feed dealer 'may need a supplemental application' and in that connection one consideration is whether 'new drug applications carry a commitment to sell only to holders of new drug applications, or holders of supplements.' The application held by Salsbury's Laboratories in the instant case has no such restriction.

"In regard to the persons required to file applications Mr. Franklin D. Clark, Assistant to the Deputy Commissioner, stated that unless exempted operators of domestic firms involved in the manufacture of drug products must register and that 'those engaged in either interstate or intrastate commerce are included.' As to criminal penalties he stated: 'For domestic firms failure to register is a prohibited act and makes the owner subject to the criminal pro-

visions of the statute. Drugs produced in an unregistered establishment are misbranded.'

"Dr. Charles G. Durbin stated in part:

> Veterinary drug manufacturers and feed mills producing *medicated feeds* will be required to register under the Act.

"No participant in the Conference, however, suggested that there was any duty on any manufacturer shipping a new drug to a dealer to ascertain the manner in which the dealer would use the drug, nor whether such dealer did or did not have an application.

"It would seem to the writer therefore that had Congress intended such a restriction it would have said so. In connection with other subject matters Congress has done so, as illustrated by in rem statutes covering equipment and products intended for use in illicit distilleries, etc., where possession of equipment or ingredients are had for the purpose of manufacturing liquor with the purpose of evading taxes thereon.

"Claimants objections to Interrogatories No. 7 and No. 8 are therefore sustained.

"As to objections by claimant to Interrogatories No. 11 to No. 18:

"All of these interrogatories relate to the manufacture and the nature of 'Strain's Broiler Mash Medicated.' While these interrogatories would be pertinent if that product was involved in this case they are not as the Court views this case pertinent or material as this case only involves a shipment of Unistat in possession of the claimant.

"In like manner Interrogatories No. 25 to No. 28 inclusive, pertain to the claimant's feed product concerning its sale out of the State of Georgia, names of persons having knowledge of the same, whether Unistat and penicillin is contained therein, etc. Here again the Court calls attention to the allegation in the libel that the Unistat was shipped into Georgia illegally because made 'to a feed manufacturer who holds no effective application for its use in animal feeds,' and that it was 'misbranded when introduced into and while in interstate commerce.' The labeling is complained of because it 'fails to bear adequate directions for use of drug in final dosage form,' that is to say in the form of 'Strain's Broiler Mash Medicated.' But, regardless of whether or not the last named product is or it not shipped in commerce and regardless of whether or not it is misbranded or requires a new drug application, these things cannot be said concerning the bag of Unistat now in possession of the alleged manufacturer of 'Strain's Broiler Mash Medicated.' If the last named product is subject to seizure that would present another case.

"Either party may present to the Court Orders pursuant hereto.

"This the 22nd day of April, 1963."

Pursuant to the above opinion, the court, on 5–2–63, ordered that the Government's interrogatories numbered 7 and 8, 11 through 18, and 25 through 28 be stricken. A motion for summary judgment of dismissal of the action was filed by the claimant and a motion for summary judgment of condemnation was filed by the Government. After considering the parties stipulation of facts and arguments and briefs of counsel, the court, on 8–15–63, granted defendant's motion for summary judgment, and ordered that the libel action be dismissed and that the article under seizure be surrendered to the claimant.

7887. Rawleigh beef and sheep premix and Rawleigh poultry premix. (F.D.C. No. 49099. S. Nos. 11–850/1 V.)

QUANTITY: 2 cases, each containing 4 10-lb. bags of *beef and sheep premix* and 8 cases, each containing 4 10-lb. bags of *poultry premix*, at Menands, N.Y.

SHIPPED: Prior to 4–5–63, from Freeport, Ill., by W. T. Rawleigh Co.

LABEL IN PART: (Tags) "Rawleigh Beef and Sheep Premix * * * Active Drug Ingredients Tetra alkylammonium stearate (from Dynafac) 2% Ethylenediamine Dihyriodide* .65% * * * Manufactured by The W. T. Rawleigh Company Freeport, Illinois"; "Rawleigh Poultry Premix Medicated Active Drug Ingredients Arsanilic Acid 1.98% Growth Stimulant For Poultry For use in

poultry feeds in amounts of not more than 10 pounds or less than 5 pounds per ton of complete feed. Analysis Per Pound * * * Procaine Penicillin Not less than 0.5 gms. Equivalent to 0.3 gm. of Crystalline Penicillin G (Master Standard) * * * Manufactured for the W. T. Rawleigh Company Freeport, Illinois."

ACCOMPANYING LABELING: Feeding chart entitled "Poultry Premix Ration Chart Direction Card No. 14."

RESULTS OF INVESTIGATION: Investigations showed that the labeling for the *poultry premix* directed, as one use of the article, that it be used in a concentrate for continuous feeding along with separate grains made available for selection by the animal; however, the feeding of such a resultant concentrate resulted in a higher level of arsanilic acid than set forth in the exempting regulations for antibiotic drugs for use in medicated animal feed.

LIBELED: 7–10–63, N. Dist. N.Y.

CHARGE: 502(l)—when shipped and while held for sale, the *poultry premix* purported to be and was represented as a drug composed in part of procaine penicillin and it was not from a batch with respect to which a certificate or release has been issued pursuant to section 507, and it was not exempt from such requirement under the exemption from certification regulations issued pursuant to section 507; and 505(a)—the *beef and sheep premix* was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to section 505(b) was effective with respect to such drug.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 9–9–63. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE*

7888. Various prescription drugs. (F.D.C. No. 46489. S. No. 30–401 T.)

QUANTITY: Approximately 1,100 btls. at Los Angeles, Calif., in possession of Colonial Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LIBELED: 10–6–61, S. Dist. Calif.; libel amended 11–17–61.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample—Not To Be Sold," "Physician's Sample For Clinical Use," "Physician's Sample," "Professional Sample—Not To Be Sold," "Professional Sample," "Patient's Starter Package," "Sample—Not To Be Sold," "Complimentary Sample," "Complimentary Package," or similar wording on the labels of the articles were false and misleading as applied to the articles, since such words connoted that the drugs were to be used or dispensed only by physicians in their professional practice and were not to be sold, whereas, the articles were in the possession of a pharmacist who was engaged in the business of repacking and selling them; 502(a)—the labeling of some of the articles was misleading because words such as "Professional Sample" which originally appeared on the label had been scratched out, cut out, or otherwise obliterated, thereby

*See also No. 7884.

obscuring the fact that such drugs were professional samples which may not be sold; 502(a)—the labeling of one of the drug containers was misleading in that it consisted of 2 label inserts in the container, each label specifying a different strength of the same tablet; 502(b)—some of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of their contents; 502(c)—the labels of some of the articles had been affixed to or inserted in the containers of the articles in such a manner (by folding or otherwise) that words, statements, and other information required by 502(b) (1) and (2), 502(d), 502(e) (1) and (2), and 503(b)(4), were not visible and were therefore not prominently placed thereon with such conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of use; 502(d)—some articles were for use by man and they contained derivatives of the hypnotic substance, barbituric acid, which derivatives have been, by the Secretary of Health, Education, and Welfare, after investigation, found to be and by regulations designated as, habit forming, and their labels failed to bear the name and quantity or proportion of such derivatives and in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e)—some articles were drugs not designated solely by a name recognized in an official compendium, and their labels failed to bear (1) the common or usual name of the drug, and (2) the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of some articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to 503(b)(1), and they failed to conform to one or more of the conditions of exemption as specified in regulations, such as: (a) The labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," (b) The labels failed to state the recommended or usual dosage, (c) The labels failed to state the quantity or proportion of each active ingredient, and (d) The labels failed to bear identifying lot or control numbers from which it was possible to determine the complete manufacturing history of each package of the drugs; 502(f)(2)—the labeling of some articles failed to bear such adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health, or against unsafe dosage, in such manner and form, as were necessary for the protection of users; 502(l)—some articles purported to be drugs composed wholly or in part of penicillin, streptomycin, chlortetracycline, and bacitracin, or derivatives thereof, and they were from batches with respect to which certificates had been issued but such certificates were not in effect with respect to such drugs, since the expiration dates on some of the drugs had passed, while the others had had their original labeling altered or removed in whole or in part; 503(b)(4)—some articles were drugs subject to the provisions of 503(b)(1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; 501(a)(1)—some articles consisted wholly or in part of decomposed substances; and 501(c)—some articles were not subject to the provisions of 501(b), and their strength differed from, and their purity and quality fell below, that which they purported to possess, since each container purported to have within it drugs of uniform strength, purity, and quality suitable for dispensing, whereas, in the case of some of these drugs, a container labeled as containing a single drug had within it (a) a mixture of drugs, (b) collapsed capsules whose contents had leaked out, (c)

several dosage forms of the same drug containing significantly different strengths, or (d) tablets or capsules varying in size, shape, color, or contents.

DISPOSITION: 10–28–63. Default—destruction.

DRUGS FOR VETERINARY USE*

7889. Medicated pig starter and medicated broiler mash. (F.D.C. No. 49159. S. Nos. 3–932 V, 38–427 V.)

INFORMATION FILED: 3–30–64, M. Dist. Tenn., against The Pillsbury Co., a corporation, Nashville, Tenn.

SHIPPED: Between 9–14–62 and 10–16–62, from Nashville, Tenn., to Rocky Mount, N.C., and Dothan, Ala.

LABEL IN PART: (Bag) "Pillsbury's Best PIG STARTER (HA8) Medicated For Swine Only For control of infestation of Large Roundworms (Ascaris), Nodular Worms (Oesophagostomum), and Whip Worms (Trichuris); for the prevention of bacterial swine enteritis, to stimulate feed intake, stimulate growth, improve feed efficiency, and help promote better uniformity of gains. ACTIVE DRUG INGREDIENTS Hygromycin B _____ .006 gr. (6000 units) per pound Streptomycin 37.5 grams per ton (0.01875 grams per pound) Procaine Penicillin 12.5 grams per ton (0.00625 grams per pound) 3-Nitro-4-Hydroxyphenylarsonic Acid _____ .0025% Manufactured By THE PILLSBURY COMPANY PELLET"; and (bag) "BITE Pillsbury's Best 4X Broiler Mash (AP) Medicated To aid in preventing outbreaks of coccidiosis and stimulating growth in growing chickens, when fed as directed on reverse side of this label. Active Drug Ingredient: Amprolium 1-(4-amino-2-n-propyl-5-pyrimidinyl-methyl)-2-picolinium chloride hydrochloride (Amprol) _____ 0.0125% INGREDIENTS Ground Yellow Corn, Dehulled Soybean Meal,* * * Procaine Penicillin * * * Manufactured by THE PILLSBURY COMPANY."

CHARGE: *Medicated pig starter*, 502(a)—when shipped, the statement "3-Nitro-4-Hydroxyphenylarsonic Acid _____ .0025%" contained in the labeling of the article was false and misleading since the article contained less than 0.0025 percent 3-nitro-4-hydroxyphenylarsonic acid; and 502(l)—the article purported to be and was represented as a drug, composed in part of a kind of penicillin and in part of a kind of streptomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirements as provided by regulations, since the article contained less than 0.0025 percent of 13-nitro-4-hydroxyphenylarsonic acid.

Medicated broiler mash, 502(a)—when shipped, the statement "Amprolium 1-(4-amino-2-n-propyl-5-pyrimidinyl-methyl)-2-picolinium chloride hydrochloride (Amprol) _____ 0.0125%" contained in the label of the article was false and misleading since the article contained less than 0.0125 percent amprolium; 502(a)—the labeling of the article contained false and misleading representations by reason of the article's deficiency in amprolium, in that the article was not adequate and effective in preventing outbreaks of coccidiosis in broiler chickens; and 502(l)—the article purported to be and was represented as a drug, composed in part of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirement as provided by regulations, since the

*See also No. 7887.

article contained less than 0.0125 percent amprolium; and the article also was not exempt from such requirement, since the article was a complete medicated feed prepared from a product of amprolium containing more than 0.05 percent of amprolium, and the defendant had failed to submit to the Commissioner of Food and Drugs adequate information with respect to the article as required by regulations, namely, the article was represented to be "Pillsbury's Best 4X Broiler Mash (AP)" on which information, including prescribed information with respect to the formula and the assaying of a statistically significant number of batches, had been submitted to the Commissioner for purposes of exemption of the article, and the formula used and the number of batches assayed in connection with the manufacture of "Pillsbury's Best 4X Broiler Mash (AP)" differed from that prescribed information, and no amended information describing the changes in the formula used and the number of assays performed with respect to "Pillsbury's Best 4X Best Broiler Mash (AP)" had been submitted to the Commissioner.

PLEA: Nolo contendere.

DISPOSITION: 6–8–64. $2,000 fine.

7890. Medicated feeds. (F.D.C. No. 47834. S. Nos. 3–014/15 T.)

INFORMATION FILED: 1–8–63, Dist. Md., against Sherwood Feed Mills, Inc., Baltimore, Md., E. F. Sherwood Dickinson, president, and S. Jones Dickinson, vice president.

SHIPPED: Between 6–7–61 and 9–18–61, from Baltimore, Md., to Fredericksburg, Va.

LABEL IN PART: (Bags) "Sherwood Feeds Starter-Grower Medicated Crumbles Active Drug Ingredient: Zoalene (3, 5-dinitro-o-toluamide _____ 0.0125% [or "Sherwood Feeds 21% Turkey Grower (H) 4-Nitrophenylarsonic Acid _____ 0.025%"] Manufactured By Sherwood Feed Mills, Inc., Baltimore, Md., U.S.A. 100 Lbs. Net Weight".

CHARGE: *Starter-Grower Medicated Crumbles*, 502(a)—when shipped, the statement, namely, "Zoalene * * * 0.0125%." displayed upon the bag of the article, was false and misleading, since the article contained less than 0.0125 percent of zoalene; and 502(l)—the article purported to be and was represented as a drug, composed in part of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507 and it was not exempt from such requirement as provided by regulations, since its labeling failed to bear a warning against its use in laying hens.

The above-mentioned article was also alleged to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

Turkey Grower, 502(a)—when shipped, the statement "4-Nitrophenylarsonic Acid _____ 0.025%" displayed upon the bags of the article was false and misleading, since the article contained less than 0.025 percent of 4-nitrophenylarsonic acid.

PLEA: Nolo contendere.

DISPOSITION: 4–10–64. Corporation—$1,300 total fine; each individual—$100 fine.

7891. Electromycin. (F.D.C. No. 47738. S. No. 63-469 T.)

QUANTITY: 177 pkgs. at Eau Claire, Wis.

SHIPPED: 5-25-62 and 5-29-62, from Luverne, Minn., by Northern States Laboratories.

LABEL IN PART: (Pkg.) "NS 50 Gallon Size Improved Electromycin A Penicillin-Streptomycin Vitamin Mixture with Added Minerals (Electrolytes) For Poultry * * * Net Weight 8 Oz. Northern State Laboratories Luverne, Minnesota."

LIBELED: 7-19-62, W. Dist. Wis.

CHARGE: 502(a)—when shipped, the name of the article, "Electromycin" and the label statement "with Added Minerals (Electrolytes)," were false and misleading in that they represented and suggested that the article had special or unusual value because of the minerals present therein; and 502(l)—the labeling of the article was false and misleading in that the article was represented as a drug, composed in part of a kind of penicillin and a kind of streptomycin (with added vitamins and minerals), and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507 and it was not exempt from that requirement since the article contained vitamins and minerals and its labeling bore statements and representations which are not permitted by the exempting regulations.

DISPOSITION: 5-6-64. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7892. Amphetamine sulfate tablets and capsules. (F.D.C. No. 48211. S. No. 94-703 T.)

QUANTITY: Approximately 1,000 tablets and capsules at Joplin, Mo., in the possession of Mark's Motor Port No. 2.

SHIPPED: Prior to 8-30-62, from places outside the State of Missouri.

LIBELED: 8-30-62, W. Dist. Mo.

CHARGE: 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—its label failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement since it was in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since such article was not to be dispensed upon prescription; and 503(b)(4)—the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-17-62. Default—destruction.

7893. Impotex. (F.D.C. No. 48939. S. No. 41-254 V.)

QUANTITY: 2,552 boxes, each containing 1 vial of a powdered substance and 1 5-cc. vial of a liquid substance, at Peekskill, N.Y., in possession of Whittaker Laboratories, Inc.

*See also No. 7888.

SHIPPED: The article was manufactured in part, from chorionic gonadotropin which was shipped on 3–16–61, from Chicago, Ill.

LABEL IN PART: (Box) "Multiple Dose Vial * * * Double Strength Impotex For The Male When Mixed each cc contains: Chorionic Gonadotropin 500 I.U., Thiamine Hydrochloride 25 mg., Vitamin B_{12} 30 mcgm., Procaine Hydrochloride 1%, * * * For Intramuscular Use Only Made For Whittaker Laboratories, Inc. * * * Directions for mixing inside. Caution: Federal law restricts this device to sale by or on the order of a physician"; (vial) "Impotex Chorionic Gonadotropin 2500 I.U. (dried) * * * See insert Made for Whittaker Labs., Inc." and "Impotex Diluent * * * See Insert Made For Whittaker Laboratories, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Impotex for the Male."

RESULTS OF INVESTIGATION: The active drug ingredient, chorionic gonadotropin, was shipped in sealed, labeled vials, from Illinois to a private laboratory in Queens Village, N.Y., where the diluent was manufactured and packed and the entire article shipped to the dealer, Whittaker Laboratories, Inc. The dealer repacked the article, inserting the leaflets and applying a sticker label containing the "Caution" statement.

LIBELED: 5–6–63, S. Dist. N.Y.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from that requirement since it failed to bear adequate information for its use, including effects and any relevant hazards, contraindication and side effects and precautions under which practitioners could use the drug safely and for the purpose for which it was intended, including all the purposes for which it was advertised or represented; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement: "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–5–63. Consent—destruction.

7894. Diu-K tablets. (F.D.C. No. 50037. S. No. 86–663 A.)

QUANTITY: 9 15,000-tablet drums and 262 100-tablet btls., at Memphis, Tenn., in possession of Edwards Pharmacal Co.

SHIPPED: 8–7–59, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Edwards 100 Diu-K Tablets Each Enteric Coated Tablet Contains: Potassium Chloride 10 Grains—Distributed By Edwards Pharmacal Company, Memphis Tenn."

ACCOMPANYING LABELING: Package insert entitled "Edwards Diu-K Tablets."

RESULTS OF INVESTIGATION: The article had been repacked by the dealer into bottles from the drums shipped as above. Analysis showed that, when tested in accordance with U.S.P. standards, the article failed to disintegrate in the allotted time.

LIBELED: 4–10–64, W. Dist. Tenn.

CHARGE: 501(b)—while held for sale, the article purported to be a drug, the name of which is recognized in the United States Pharmacopoeia, and its quality fell below the standard set forth in such compendium; 502(a)—the article was enteric coated and the label statements, (drum) "Tablets—Potassium Chloride USP" and (btl.) "Each Enteric Coated Tablet Contains: Potassium Chloride," were false and misleading as applied to an article which failed to meet the disintegration requirements of the United States Pharma-

copoeia for enteric-coated potassium chloride tablets; and (repack) 503(b)(4)—the article was a drug subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5–15–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

7895. Food supplements and laxative tablets. (F.D.C. No. 47891. S. No. 16–225 T.)

INFORMATION FILED: 2–6–63, S. Dist. Ohio, against Garriott L. McClellan, Cincinnati, Ohio.

ALLEGED VIOLATION: 10–24–61, while quantities of *herbal laxative tablets, calcium complex tablets, vitamin C tablets, vitamin-mineral capsules,* and *protein wafers,* were being held for sale after shipment in interstate commerce, the defendant did, at Cincinnati, Ohio, in the course of a sales talk, make oral representations regarding diseases, conditions, and purposes for which the articles were intended, which act resulted in the articles being misbranded.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use in the treatment and prevention of heart attacks, arthritis, hemorrhoids, cerebral hemorrhages, varicose veins, spinal meningitis, muscle spasms, cankers, asthma, fever blisters, lobar pneumonia, hypertension, inflammation, leukemia, whooping cough, bad teeth, menstrual cramps, and colds; and to promote hormone balance, good circulation, proper metabolism, proper blood pressure, and healthy blood; which were the diseases, conditions and purposes for which the articles were intended, prescribed, recommended, and suggested in the course of the sales talk given by Garriott L. McClellan.

PLEA: Guilty.

DISPOSITION: 3–8–63. $200 fine suspended.

7896. Nutri-Bio food supplement. (F.D.C. No. 49230. S. No. 15–333 X.)

QUANTITY: 266 pkgs., each containing 26 7-day-supply envelopes, and 24 pkgs., each containing 4-week-supply packets, at Jeffersonville, Ind., in possession of Thomas Gordon Railey.

SHIPPED: 11–3–61, from Beverly Hills, Calif., by Nutri-Bio Corp.

LABEL IN PART: (Pkg. sleeve) "728 Mineral Tablets 364 Vitamin Tablets Nutri-Bio * * * dietary food supplement * * * 2 Vitamin Tablets and 4 Mineral Tablets Daily will supply * * * Vitamin C * * * 60 mg. * * * Formulated for and Distributed by Nutri-Bio Corporation * * * Beverly Hills, Calif."

ACCOMPANYING LABELING: Booklets entitled "Nutri-Bio" and "Why a food supplement"; leaflets entitled "The 'Improved' Natural or Organic Vitamin and Mineral Food Supplement," "Do You Know," and "The Nutri-Bio Program For Better Living"; chart entitled "A Nutri-Bio Product For Everyone For

*See also Nos. 7881, 7883, 7884, 7888, 7892, 7893.

Balanced Nutrition"; a series of colored slides entitled "Just To Be Sure" with a coordinated, recorded narration; and a number of sales manuals.

RESULTS OF INVESTIGATION: Analysis showed that the 266-package lot of the article contained between 40 and 55 percent of the declared amount of vitamin C.

LIBELED: 8-30-63, S. Dist. Ind.

CHARGE: 266-pkg. lot, 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "2 Vitamin Tablets and 4 Mineral Tablets Daily will supply * * * Vitamin C * * * 60 mg." was false and misleading as applied to a product containing less than the declared amount of vitamin C.

266-pkg. lot and 24-pkg. lot, 502(a)—when shipped, the label and the accompanying labeling of the article contained false and misleading representations that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, herperidin complex, choline, alfalfa juice and powder concentrate, copper, zinc, manganese, magnesium potassium, sulfur, chlorine, and montmorillonite (wonder clay), and because the ingredients of the article were of natural or organic origin; 502(a)—the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of nervousness, loss of appetite, loss of weight, dental caries, anemia, palpitation of the heart, pyorrhea, excessive bleeding from minor wounds, muscular spasm, and osteoporosis; to promote mental and physical health, happiness, sociability, enthusiasm, liveliness, vigor, alertness, and awareness; and to build and rebuild the body; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the treatment and prevention of baldness, heart attack, serious heart condition, to feel younger, strokes, swollen knees and ankles, asthma, allergies, and to promote longer life; which were the conditions and purposes for which the article was intended, prescribed, and recommended in a sales talk made by Thomas Gordon Railey, on or about 6-25-63, at his home and place of business, to a Food and Drug Inspector who visited the dealer incognito.

DISPOSITION: 10-9-63. Default—destruction.

7897. Regimen tablets. (F.D.C. No. 46971. Inj. No. 483. S. Nos. 21-050/1 T.)

QUANTITY: 137 78-tablet boxes and 63 156-tablet boxes at Denver, Colo.

SHIPPED: Between 5-10-61 and 1-16-62, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction By Appetite Control Regimen-Tablets * * * contain;—(in Green tablets) Vitamin D. (irradiated yeast), B_1, B_2, B_6 and C, Niacinamide, Calcium Pantothenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride, Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Amonium Chloride. * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular in box reading in part "Reduce with the Regimen Plan: A New Dietary Combination to Satisfy Hunger Remove Excess Water Control and Inhibit Appetite Drug Research Corp. New York, New York * * * As long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss"; and display carton

reading in part "New! Regimen-Tablets for Appetite Control * * * A New 3-Way Drug Combination for Weight Reduction * * * Excess Weight Reduction by Appetite Control"; and counter display piece reading in part "Leading Physicians show Regimen Tablets Can Help You Reduce as much as 6½ Pounds in 7 Days—19 Pounds in 6 Weeks without planned dieting!"

RESULTS OF INVESTIGATION: The counter display piece had been a newspaper advertisement in a local paper, which advertisement had been sponsored by the shipper.

LIBELED: 2–13–62, Dist. Colo.; libel amended 7–3–63.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would cause one to reduce as much as 6½ pounds in 7 days and 19 pounds in 6 weeks without planned dieting; that the article would satisfy hunger, control and inhibit appetite, and shrink one's appetite, causing pounds and inches to melt away; that the article had been proved amazingly effective in clinical tests on overweight people; that the article consisted of a combination of reducing drugs so amazing that one could lose weight without planned dieting; that the use of the article would cause unwanted pounds and inches to roll off; that clinical tests showed dramatic results; that people had lost as much as 3 pounds the first 3 days; that the loss of weight would be sustained; that use of the article would cause one to slim down and remain slim; that with the article one must lose up to 6 pounds in just days, many more pounds thereafter; that the article could cause one to lose weight without planned dieting; that excessive weight made cirrhosis of the liver much more possible than in slender folks and that it had been shown that fat people were more susceptible to cancer; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use of the article for the purposes for which it was intended, namely, for the purpose of reducing and maintaining, permanently, losses of as much as 6½ pounds in 7 days and 19 pounds in 6 weeks without planned dieting, while enjoying with "gusto" one's favorite foods; and for the purpose of losing 7 pounds the first week, 25 pounds in 5 weeks without drastic change in eating habits; which statements appeared in newspaper advertisements sponsored by, and intended by, the shipper of the article, to be used in promotion of the article at point of sale.

DISPOSITION: On 3–26–62, the article was claimed by Drug Research Corp., New York, N.Y., and an answer was filed by Drug Research Corp., denying that the article was misbranded. On 5–28–62, pursuant to stipulation of the parties, the case was removed to the Eastern District of New York. On 10–15–62, the Government served written interrogatories upon the claimant and these were answered by Drug Research Corp., on 12–26–62. On 2–6–63, the claimant served written interrogatories on the Government; and thereafter the Government answered these interrogatories. On 6–20–63, the Government filed a motion to amend the libel so as to charge that the accompanying labeling of the article contained the false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite, and also to include a prayer for injunctive relief. On 7–3–63, the court granted the Government's motion. On 8–27–63, claimant filed an answer to the Government's amended libel. On 12–30–63, a Consent Decree of Condemnation and Injunction was filed which

ordered that the seized article together with all written, printed, or graphic matter seized therewith be destroyed; that claimant pay court costs and fees and storage and other proper expenses, including specifically the costs of taking depositions; and that Drug Research Corp. was permanently enjoined and restrained from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction into interstate commerce, or holding for sale or causing to be held for sale after shipment in interstate commerce, the drug "*Regimen*," or the same drug by any other designation, or any similar drug which:

(a) Is accompanied by any written, printed or graphic matter which contains statements which represent and suggest that "*Regimen*" is adequate and effective for weight reduction and control by curbing and controlling the appetite; that "*Regimen*" will cause one to reduce as much as 6½ pounds in 7 days and 19 pounds in 6 weeks without planned dieting; that "*Regimen*" will satisfy hunger, control and inhibit appetite, or shrink one's appetite; that "*Regimen*" has been proved amazingly effective in clinical tests on overweight people; that "*Regimen*" consists of a combination of reducing drugs so amazing that one can lose weight without planned dieting; that use of "*Regimen*" will cause unwanted pounds and inches to roll off; that clinical tests show dramatic results; that people have lost as much as 3 pounds the first 3 days; that loss of weight will be sustained, that use of "*Regimen*" will cause one to slim down and remain slim; that with "*Regimen*" one must lose up to 6 pounds in just days, many more pounds thereafter; that "*Regimen*" can cause one to lose weight without planned dieting; or that excessive weight makes cirrhosis of the liver much more possible than in slender folks and that it has been shown that fat people are more susceptible to cancer; or any similar statement or any other statement which is false, misleading, or ambiguous; or

(b) Fails to bear or be accompanied by labeling which states each and every purpose and condition for which "*Regimen*" is intended to be used or for which it is, by any means, represented to the public to be effective, together with sufficient information to enable the layman to use the drug intelligently, safely, and effectively for each such purpose and condition.

7898. Various prescription drugs. (F.D.C. No. 48064. S. Nos. 89–520/6 T, 89–530 T.)

QUANTITY: An undetermined number of vials, btls., and other pkgs. of drugs, at Royal Oak, Mich., in possession of Royal Drug Corp.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample Not To Be Sold," "Professional Sample," "Physician's Sample," "Physician's Professional Package," and "Sample: Not To Be Sold."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which were repacked by the dealer, Royal Drug Corp., from physicians' samples into packages to which had been affixed labels bearing brand names of drugs as were indicative of their manufacture outside the State of Michigan, a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Michigan; and some of the articles were prescription drugs which had not yet been repacked by the dealer, which consisted of drugs in containers bearing brand names of the drugs as were indicative of their manufacture outside the State of Michigan, a "complimentary—not for sale" professional sample

legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Michigan.

LIBELED: 8–30–62, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample Not To Be Sold," "Physician's Sample," "Physician's Professional Package," "Sample: Not To Be Sold," "Professional Sample" and similar wording on the labels of some of the articles, were false and misleading as applied to the articles which were then in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; and 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were drugs subject to provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations.

DISPOSITION: 10–10–62. Default—destruction.

7899. Various prescription drugs. (F.D.C. No. 48956. S. Nos. 78–302/7 V, 88–123/9 V.)

QUANTITY: 6 1,000-tablet btls. of white 10-mg. *dextro-amphetamine sulfate tablets*, 3 1,000-tablet btls. of white 1½-gr. *phenobarbital tablets*, 9 1,000-capsule btls. of yellow 1½-gr. *pentobarbital sodium capsules*, 1 100-capsule btl. of yellow *pentobarbital sodium capsules*, 6 1,000-capsule btls. of red 1½-gr. *secobarbital sodium capsules*, 7 1,000-capsule btls. of 15-mg. *dextro-amphetamine sulfate capsules*, 9 1,000-capsule btls. of 10-mgm. *dextro-amphetamine sulfate capsules*, 1 1,000-capsule btl. of pink ¾-gr. *pentobarbital sodium capsules*, 30 1,000-tablet btls. of yellow 5-mgm. *dextro-amphetamine sulfate tablets*, 17 1,000-tablet btls. of orange 5-mgm. *dextro-amphetamine sulfate tablets*, 15 1,000-tablet btls. of white ¼-gr. *phenobarbital tablets*, 2 1,000-tablet btls. of white ½-gr. *phenobarbital tablets*, and 9 1,000-tablet btls. of ¼-gr. *butabarbital sodium tablets*, at Cleveland, Ohio, in possession of Sykes Drug & Sundries Co.

SHIPPED: Prior to 5–7–63, from Philadelphia, Pa., and Brooklyn, N.Y.

LIBELED: 5–10–63, N. Dist. Ohio.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were prescription drugs in possession of a person not lawfully engaged in distributing or dispensing prescription drugs.

DISPOSITION: 6–11–63. Default—destruction.

7900. Pyrodyn tablets and injection. (F.D.C. No. 48988. S. Nos. 15–772/3 V.)

QUANTITY: 274 100-tablet btls. of *Pyrodyn tablets*, and 86 30-cc. vials of *Pyrodyn injection*, at Nashville, Tenn.

SHIPPED: The tablets were shipped on 11–13–61, from St. Louis, Mo., by Shaw Pharmacal Co., and the injection on an unknown date during 1962 or 1963, from Decatur, Ill., by Taylor Pharmacal Co.

LABEL IN PART: (Btl.) "Pyrodyn Each tablet contains Methampyrone Sodium 0.5 Gm. Caution: * * * Manufactured for Phillips Laboratories, Inc., Nashville, Tenn. Indications: For the relief of pain and/or lowering fever." and

(ctn.) "Pyrodyn 50 Per Cent Solution * * * Methampyrone Sodium Pyrodyn 0.5 Gram per cc. in water for injection Intramuscular Intravenous Manufactured for Phillips Laboratories, Inc. Nashville, Tenn."

RESULTS OF INVESTIGATION: Analysis showed that the tablets and injection contained approximately 87 percent and 95 percent, respectively, of the declared amount of methampyrone sodium.

LIBELED: 5–23–63, M. Dist. Tenn.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since their labeling failed to conform to the requirements of the exemption regulations applicable to prescription drugs.

DISPOSITION: 7–8–63. Default—destruction.

7901. Triphyton fungicide. (F.D.C. No. 49969. S. No. 1–180 A.)

QUANTITY: 6 5-gal. jugs, 57 4-oz. btls., and 55 1-pt. btls., at Tucker, Ga., in possession of DeKalb Pharmaceuticals, Inc.

SHIPPED: 3–28–64, from Greenville, S.C.

LABEL IN PART: (Btl.) "Triphyton (topical fungicide) * * * Directions: Twice daily * * * Contents: sodium propionate 2%, sodium caprylate 2%, propionic acid 3%, undecylenic acid 5%, salicylic acid 5%, copper undecylenate 0.5%, dioctyl sodium sulfosuccinate 0.1% * * * Distributed by DeKalb Pharmaceuticals, Inc., Tucker, Ga."

ACCOMPANYING LABELING: Package insert entitled "Triphyton (topical fungicide)."

RESULTS OF INVESTIGATION: The article was shipped in a bulk drum and repacked by the dealer into the jugs and bottles described above.

LIBELED: On or about 4–15–64, N. Dist. Ga.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a fungicide, and that it was nonsensitizing and nonirritating; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the lay user for all the conditions for which it was represented.

DISPOSITION: 5–18–64. Default—destruction.

7902. Preparation H laxative tablets. (F.D.C. No. 49479. S. No. 601 X.)

QUANTITY: 3,816 individually ctnd. 30-tablet btls., at Forest Park, Ga.

SHIPPED: Between 2–1–63 and 4–30–63, from Elkhart, Ind., by Whitehall Laboratories, Inc.

LABEL IN PART: (Ctn.) "Preparation H Special Laxative * * * For Constipation Relief of Hemorrhoid Sufferers * * * Directions * * * Warning * * * Preparation H Special Laxative Tablets * * * Each tablet contains dioctyl sodium sulfosuccinate 100 mg.; acetphenolisatin 5 mg. * * * Whitehall Laboratories, Inc. New York, N.Y."

ACCOMPANYING LABELING: Display carton reading in part "Recommend Preparation H Special Laxative to all your Hemorrhoidal Remedy Customers Whitehall Laboratories, Inc. New York, N.Y. * * * New! Preparation H Special Laxative Tablets for constipation relief of Hemorrhoid Sufferers * * * Made by the makers of Preparation H"; and carton insert reading in part "Preparation H Special Laxative Relieves Constipation Without Pain For Hemorrhoid Sufferers."

LIBELED: 10–21–63, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for pain connected with hemorrhoids; relieved constipation without pain; helped maintain a healthy punctuality; made bowel movements as effortless and painless as possible; that the article acted without irritation of harsh laxatives and avoided pressure, straining, and irritation which aggravate hemorrhoids; and that the dioctyl sodium sulfosuccinate present in the article was a regulator; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use since adequate directions cannot be written for use of the article for the conditions for which it was intended, namely, for use in pregnancy, a condition in which the safe and effective use of the article requires professional supervision, and for use for rectal fissure, a condition not amenable to lay-diagnosis.

DISPOSITION: 1–28–64. Default—destruction.

7903. Rependo capsules. (F.D.C. No. 49447. S. No. 17–685 X.)

QUANTITY: 1 box of 10,000 capsules, 6 btls. of 1,000 capsules each, and 454 btls. of 100 capsules each, at Columbus, Ohio, in possession of Standex Laboratories, Inc.

SHIPPED: 6–3–63, from Detroit, Mich., in bulk and thereafter repacked in part into bottles, by Standex Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Capsules REPENDO each capsule contains Hesperidin Methyl Chalcone 100 MGM, Vitamin C 100 MGM, Menadione .1 MGM, Distributed by Standex Laboratories, Inc., Columbus, Ohio. Warning Federal Law Prohibits * * * Control H–2001."

ACCOMPANYING LABELING: Physician file cards reading in part "REPENDO for Capillaries * * * Standard Laboratories, Inc., Columbus, Ohio."

LIBELED: 11–13–63, S. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of fragile capillaries, habitual abortion, ecchymosis, retinal hemorrhage, purpura, radiation sickness, noninfectious albuminuria, conditions manifesting excessive permeability, discontinuity of other endothelial structures, capillary rupture, and to strengthen endothelial membranes wherever found; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, since the labeling failed to bear adequate information for use including relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the article can use the article safely and for the purposes for which it was intended.

DISPOSITION: 1–21–64. Default—destruction.

7904. Tonsiline solution. (F.D.C. No. 49104. S. Nos. 88–131/4 V.)

QUANTITY: 668 2-oz. btls. and 465 4-oz. btls. at Detroit, Mich.

SHIPPED: Between 3–1–63 and 4–26–63, from Canton, Ohio, by Tonsiline Co.

LABEL IN PART: (Btl.) "Tonsiline Active Ingedients: Potassium Chlorate, Iron Chloride, Glycerite of Boroglycerin and Balsam Tolu. * * * For Minor Irritations of the Throat and Mucous Membranes of the Mouth & Hoarseness Due To Colds Dust, Fumes, Excessive Speaking Or Smoking The Tonsiline Co. Canton, Ohio."

RESULTS OF INVESTIGATION: Analysis indicated that the article contained approximately 769 mgs. of potassium chlorate per fluid ounce.

LIBELED: 7-10-63, E. Dist. Mich.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and adequate directions for safe and effective use of the article, internally, cannot be written; and 502(f)(2)—the labeling of the article failed to bear the warning that severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea and vomiting may be serious and that a physician should be consulted promptly; that the article was not to be used for more than 2 days or administered to children under 3 years of age unless so directed by a physician; and the warning for articles containing chlorates, to avoid swallowing.

DISPOSITION: 9-20-63. Default—destruction.

7905. Bichloracetic Acid Kahlenberg Treatment Kit. (F.D.C. No. 49490. S. No. 1-827 X.)

QUANTITY: 170 kits, each containing 2 16-gm. btls., 2 vials, and applicator sticks, at Sarasota, Fla., in possession of Kahlenberg Laboratories, Inc.

SHIPPED: The article was manufactured in part from raw materials, namely, bichloroacetic acid, monochloroacetic acid, and hydrochloric acid, which had been shipped on 8-7-62, 11-16-62, and other unknown dates, from Midland, Mich., and Wilmington, Del.

LABEL IN PART: (Kit) "Treatment Kit * * * Bichloracetic Acid Kahlenberg with Special Petrolatum For Chemical Cauterization of Skin and other Tissue Contains Acid Receptacles, Applicators, Micro Dropper and Directions Caution: Federal law prohibits dispensing without prescription. Kahlenberg Laboratories, Inc. Sarasota, Florida, U.S.A."; (btl.) "Bichloracetic Acid For Chemical Cauterization of Skin and other Tissue Kahlenberg Laboratories, Inc. Sarasota, Florida, U.S.A." and "Petrolatum For Use with Bichloracetic Acid Kahlenberg Kahlenberg Laboratories, Inc. Sarasota, Florida, U.S.A."

ACCOMPANYING LABELING: Booklets entitled "Directions Bichloracetic Acid Kahlenberg"; leaflets entitled "Professional Prices, Direct Kahlenberg Laboratories, Inc., Box 160, Sarasota, Fla.," "New * * * from Kahlenberg for prompt, efficient cauterization of skin and other tissue," "Kahlenberg Laboratories, Incorporated," and beginning "Dear Doctor:" and "August, 1962 Bichloracetic Acid Kahlenberg."

LIBELED: 11-8-63, M. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for pigmented blotches, boils, basal cell carcinoma, cysts, erosions, and polyps of the cervix, endocervicitis, external hemorrhoids, leukoplakia, nevi, intractable anal pruritus, tonsil ulcers, and many other types of lesions; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since its labeling failed to bear adequate information for its use, including all indications, effects, methods, relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the article could use the article safely for the purposes for which it was intended, since (1) the labeling failed to inform the practitioner that its use in the treatment of pigmented blotches and nevi may be contraindicated in premalignant or

malignant lesions; (2) it failed to mention the hazards and contraindications of this method of treatment for boils; (3) it failed to bear contraindications and relevant hazards in the treatment of leukoplakia since it failed to mention that this condition is often malignant; (4) the directions for use in the treatment of basal cell carcinoma were inadequate, and adequate directions for such use cannot be written since the article cannot be safely used for such condition; (5) the directions for use in the treatment of cysts, erosions, and polyps of the cervix, and endocervicitis were inadequate because contraindications (malignancy) and cautions under which the practitioner could safely administer the article were not given; (6) the directions for use of the article for external hemorrhoids and intractable anal pruritus were inadequate, and adequate directions for such conditions cannot be written since the article was not adequate and effective for such conditions; and (7) the directions for use of the article in the treatment of tonsil ulcers were inadequate, and adequate directions cannot be written for such use since all ulcers are symptoms of other conditions for which the article was not adequate or effective.

DISPOSITION: 2–20–64. Default—destruction.

7906. Micro-Dynameter device. (F.D.C. No. 48301. S. Nos. 71–825/6 T.)

QUANTITY: 1 device at Paducah, Ky., and 1 device at Murray, Ky.

SHIPPED: Between 10–4–53 and 10–4–62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: (Metal plate) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

ACCOMPANYING LABELING: Literature pertaining to the *Micro-Dynameter device.*

RESULTS OF INVESTIGATION: Examination indicated that each device was essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude. The device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 10–20–62, W. Dist. Ky.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease, and the article was not adequate and effective for such purpose; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 12–31–62. Default—destruction.

7907. Micro-Dynameter devices (6 seizure actions). (F.D.C. Nos. 47954, 48003, 48007, 48021, 49954. S. Nos. 63–938 T; 17–878 T; 89–016 T; 58–144 T, 58–145 T; 56–396/7 A.)

QUANTITY: 1 device at Coral Gables, Fla.; 1 device at Indianapolis, Ind.; 1 device at Detroit, Mich.; 1 device at Greenfield, Ind.; 1 device at Knightstown, Ind.; and 2 devices at Wichita, Kans.

SHIPPED: Between 1–1–48 and 6–30–62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: (Panel) "Manufactured by Ellis Research Laboratories, Inc. Chicago * * * The Ellis Micro-Dynameter."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

LIBELED: 8–20–62, S. Dist. Fla.; 9–6–62, S. Dist. Ind.; 8–28–62, E. Dist. Mich.; 9–6–62, S. Dist. Ind.; 9–6–62, S. Dist. Ind.; and on or about 4–14–64, Dist. Kans.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective in the diagnosis of disease; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 12–15–62; 10–18–62; 10–12–62; 10–18–62; 10–18–62; and 5–28–64. Default—1 device delivered to the Food and Drug Administration; 5 devices destroyed.

7908. Micro-Dynameter devices. (F.D.C. No. 47935. S. Nos. 63–822 T, 63–824 T.)

QUANTITY: 2 devices, at Macon and Eatonton, Ga.

SHIPPED: Between 1–1–59 and 12–31–59, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

LIBELED: 8–9–62, M. Dist. Ga.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 10–24–62. Default—destruction.

7909. Micro-Dynameter device. (F.D.C. No. 48005. S. No. 31–982 T.)

QUANTITY: 1 device at Las Vegas, Nev.

SHIPPED: Between 6–1–59 and 6–30–59, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

LIBELED: 8–30–62, Dist. Nev.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the article failed to bear

adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 11–16–62. Consent—delivered to the Food and Drug Administration for investigational and exhibit purposes, and to be maintained intact and available under court process to Ramsarut Maraj, D.C., the original purchaser of the device, if such device should be needed in litigation between Dr. Maraj and the firm from whom he had purchased the device.

7910. Research Model device. (F.D.C. No. 48017. S. No. 60–662 T.)

QUANTITY: 1 device at Grundy Center, Iowa.

SHIPPED: 8–14–62, from Elkhart, Ind., by H.C. Lindahl.

LABEL IN PART: "Research Model."

RESULTS OF INVESTIGATION: Investigation indicated that the *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support.

LIBELED: 8–30–62, N .Dist. Iowa.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10–10–62. Default—destruction.

7911. Research Model device. (F.D.C. No. 48088. S. No. 12–079 T.)

QUANTITY: 1 device at West Bend, Wis.

SHIPPED: Prior to 8–30–62, from Tiffin, Ohio.

RESULTS OF INVESTIGATION: Only the dial face of the device was seized since the remainder of the device had been destroyed by the dealer.

LIBELED: 9–4–62, E. Dist. Wis.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of this article for such purpose.

DISPOSITION: 10–2–62. Default—destruction.

7912. Research Model devices. (F.D.C. No. 47824. S. Nos. 34–283/5 T.)

QUANTITY: 4 devices at Cumberland, Wis.

SHIPPED: 6–30–62 and 7–2–62, from St. Paul and South St. Paul, Minn. These were return shipments.

LIBELED: 8–16–62, W. Dist. Wis.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use

for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10–13–62. Default—delivered to the Food and Drug Administration.

7913. Research Model device. (F.D.C. No. 48000. S. No. 95–819 T.)

QUANTITY: 1 device at Buffalo, N.Y.

SHIPPED: Prior to 8–21–62, from Cumberland, Wis., by Toftness Chiropractic Clinic.

LABELS IN PART: "Research Model Serial No. 47B" and "Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic."

LIBELED: 8–27–62, W. Dist. N.Y.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10–31–62. Default—destruction.

7914. Research Model devices (3 seizure actions). (F.D.C. Nos. 47682, 47685, 47968. S. Nos. 10–919 T; 4–697 T; 10–857/8 T.)

QUANTITY: 5 devices, at Newport News, Va., and Orchard Park, Hamburg, and Buffalo, N.Y.

SHIPPED: On various dates, from Cumberland, Wis., by Toftness Post Graduate School of Chiropractic, Inc., Foundation for the Advancement of Chiropractic Research, Inc., and Toftness Chiropractic Clinic.

LABELS IN PART: "Research Model" and "This instrument has no known analytical or therapeutic value."

LIBELED: Between 6–22–62 and 8–17–62, W. Dist. N.Y., and E. Dist. Va.

CHARGE: 502(a)—when shipped, the labeling of the articles contained statements which were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of practitioners in chiropractic; 502(b)(1)—the labeling of the articles failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10–31–62; 8–13–62; 10–31–62. Default—destruction.

7915. Research Model device. (F.D.C. No. 47961. S. No. 200 T.)

QUANTITY: 1 device at St. Petersburg, Fla.

SHIPPED: Between 2–1–62 and 3–31–62, from Cumberland, Wis., by Toftness Post Graduate School of Chiropractic, Inc.

LABEL IN PART: "Research Model * * * Limitation of use: This instrument has no known therapeutic, diagnostic or analytical value and shall not be

used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic. Manufactured for and leased for research purposes only by Toftness Post Graduate School of Chiropractic, Inc., * * * Cumberland, Wisconsin."

ACCOMPANYING LABELING: Leaflet entitled "The Toftness System of Spinal Correction Copyright 1955 I.N. Toftness, D.C., Cumberland, Wis."

LIBELED: 8–16–62, S. Dist. Fla.

CHARGE: 502(a)—when shipped, the above-mentioned label statements were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 1–3–63. Default—destruction.

7916. Neurolinometer devices and Research Model device. (F.D.C. No. 48015. S. Nos. 70–401/2 T.)

QUANTITY: 2 *Neurolinometers* and 1 *Research Model*, at Wahpeton, N. Dak.

SHIPPED: Between 1–1–58 and 8–29–62, (*Research Model*) from Cumberland, Wis., by the Foundation for the Advancement of Chiropractic Research, Inc., and (*Neurolinometer*) from Virginia, Minn.

LABELS IN PART: "Neurolinometer Toftness System Cumberland, Wisconsin and "Research Model 110 Volts A.C. This instrument has no known analytical or therapeutic value."

RESULTS OF INVESTIGATION: The *Neurolinometer* was a device housed in a black suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

LIBELED: 8–31–62, Dist. N. Dak.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose, and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10–29–62. Default—delivered to the Food and Drug Administration.

7917. Halox generator device. (F.D.C. No. 48138. S. No. 85–641 T.)

QUANTITY: 1 device at Menlo Park, Calif.

SHIPPED: Some time in 1958, from Summit, N.J., by Anthony Caporaso.

LABEL IN PART: (Panel) "Halox Therapeutic Generator" and (metal plate on back of device) "Halox Therapeutic Generator Co. * * * Scientific Chlorine Inhalators * * * Central, New Mexico."

ACCOMPANYING LABELING: Book entitled "The Miracles of Father Aull."

RESULTS OF INVESTIGATION: Inspection indicated the article to be designed as a portable cabinet containing components capable of producing chlorine gas from table salt by means of electrolysis.

LIBELED: 10–2–62, N. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use in overcoming various disease conditions for which the article was recommended, and it was not feasible to devise adequate directions for use, since the article as designed was worthless for any medical purpose.

DISPOSITION: 1–17–63. Default—delivered to the Food and Drug Administration.

7918. Various devices. (F.D.C. No. 49615. S. Nos. 18–066/70 V.)

QUANTITY: 1 *Pathoclast device*, 1 *Cardiolectameter device*, 1 *Electronic Magnetic Model G device*, and 2 *Pathosine devices*, at Midwest City, Okla., in possession of King Health Clinic (George E. King, naturopath).

SHIPPED: On unknown dates prior to 4–13–62, from Chicago, Ill., Denver, Colo., Tiffin, Ohio, and North Hollywood, Calif.

RESULTS OF INVESTIGATION: The *Pathoclast* was a desk console-type, electrically operated diagnostic and therapeutic device, with a control panel and circuitry on top of the desk, containing a variety of meters, knobs, dials, switches, lights, and specimen wells for the operation of the device, and the electronic components of such device were intended to measure the electrical vibrations from the body and reradiate similar radiations through the electrodes to the body.

The *Cardiolectameter* was a wood console-type, electrically operated diagnostic and therapeutic device, with a control panel containing a series of switches, a rheostat dial, meters and a speaker which emitted sounds representing circulatory pressure. The device contained numerous wires, a speaker, tubes and other electrical parts. The name plate on the front read "Cardiolectameter Reg. U.S. Patent Office Pat. Pending Denver Colo. Made in U.S.A."; the rear panel read "Cardiolectameter designed to operate on A.C. current only 60-cycle 110 volts Model H. No ———."

The *Electronic Magnetic Model G* was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. There were electronic components within the case for a power supply, oscillators, and amplifier for the detection and/or operation of hertzian waves.

The *Pathosine* was a wood and metal console-type, electrically operated therapeutic device. The control panel contained a series of dials, switches, lights, and plug outlets. Used as accessories with the device were electrodes and pads. The electrical components of such device were intended to measure and perform therapy to eyes and muscles for diseases determined by the device.

LIBELED: 11–22–63, W. Dist. Okla.

CHARGE: 502(f)(1)—while held for sale, the labeling of the *Cardiolectameter* and *Pathosine* failed to bear adequate directions for use and they were not exempt from such requirements, since they were not labeled in accordance with the labeling requirements of the exempting regulations; the labeling of the *Pathoclast* and *Electronic Magnetic Model G* failed to bear adequate directions

for use and it was not feasible to devise adequate directions for use of such devices.

DISPOSITION: 1–17–64. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE*

7919. Medicated feed. (F.D.C. No. 49635. S. No. 62–726 X.)

QUANTITY: 72 50-lb. bags, at Clay Center, Kans., in possession of Key Milling Co., Inc.

SHIPPED: An active drug ingredient of the article, arsanilic acid, had been shipped from Charles City, Iowa, on an unknown date.

LABEL IN PART: (Tag on bag) "Keytone Medicated 1. For the prevention of chronic respiratory disease (Air-sac infection) and hexamitiais in poultry, and swine enteritis when fed continuously. * * * Active Drug Ingredients Chlortetracycline (Aureomycin) equivalent to Chlortetracycline Hydrochloride .50 grams per pound (100 grams per ton). 3-Nitro-4 Hydroxyphenylarsonic Acid 0.01% * * * Manufactured by Key Milling Co., Inc. Clay Center, Kansas."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately .022 percent of arsanilic acid. Inspection of the manufacturer showed that arsanilic acid had been substituted for 3-nitro-4-hydroxyphenylarsonic acid. The article had been manufactured by the dealer who used arsanilic acid which had been shipped as above.

LIBELED: 12–20–63, Dist. Kans.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 501(d)(2)—arsanilic acid had been substituted for 3-nitro-4-hydroxyphenylarsonic acid; 502(a)—the label statement "Active Drug Ingredients * * * 3-Nitro-4 Hydroxyphenylarsonic Acid 0.01%" was false and misleading as applied to a product which contained none of this ingredient; and 502(f)(2)—the labeling of the article failed to bear a warning statement that the article may not be fed within 5 days prior to slaughter of the animal for food purposes.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–12–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE**

7920. Imitation Dexamyl Spansule capsules. (F.D.C. No. 49619. S. No. 64–832 X.)

QUANTITY: 11 250-capsule btls. at High Point, N.C.

SHIPPED: 9–6–63, from Chicago, Ill., by Biddle Purchasing Co.

LIBELED: 11–22–63, M. Dist. N.C.

CHARGE: 501(d)(2)—when shipped, imitation "Dexamyl" had been substituted for "Dexamyl"; 502(a)—the name of the article "Dexamyl" was false and misleading as applied to an imitation; 502(i)(2)—the article was an imitation

*See also No. 7886.

**See also Nos. 7888, 7894, 7896.

of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 12–31–63. Default—delivered to the Food and Drug Administration.

7921. Imitation Dexamyl Spansule capsules. (F.D.C. No. 49504. S. No. 39–757 X.)

QUANTITY: 4 250-capsule btls. at New York, N.Y.

SHIPPED: 8–29–63, from Chicago, Ill., by Biddle Purchasing Co.

LIBELED: 11–27–63, S. Dist. N.Y.

CHARGE: 501(d)(2)—when shipped, one article of drug had been wholly substituted for another; 502(a)—the name of the article "Dexamyl" was false and misleading; 502(i)(2)—the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 12–16–63. Default—delivered to the Food and Drug Administration.

7922. DaCosta "A" tablets. (F.D.C. No. 49207. S. Nos. 17–221 X, 17–223/4 X.)

QUANTITY: 217,500 tablets in various containers, at Muncie, Ind., in possession of Carr Drug Co.

SHIPPED: Between 1–19–61 and 11–8–62, from Cincinnati, Ohio.

LABEL IN PART: (Cylinders and btls.) "Nitroglycerin, Digitalis, Strophanthus and Belladonna (DaCosta 'A') Each tablet represents: Nitroglycerin 1/100 gr., Tr. Digitalis 3 min., Tr. Strophanthus (Ouabain 0.0055 gr.) 1 min., Tr. Belladonna ¼ min. * * * Caution * * * Warning * * * Dose * * * Distributed by Carr Drug Co., Inc. Muncie, Indiana."

RESULTS OF INVESTIGATION: The article had been shipped in bulk drums and had been repacked into various containers by the dealer. Analysis showed that the article contained less than the declared amount of nitroglycerin.

LIBELED: 8–6–63, S. Dist. Ind.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statements (repack) "Each tablet represents: Nitroglycerin 1/100 gr." was false and misleading as applied to a product containing less than the declared amount of nitroglycerin per tablet.

DISPOSITION: 10–3–63. Default—destruction.

7923. Bi-Nor-Ex Junior elixir. (F.D.C. No. 49112. S. No. 25–528 V.)

QUANTITY: 45 cases, each containing 12 8-oz. btls., at Detroit, Mich., in possession of Bilnor Distributors, Inc. (N&R Chemical Co.).

SHIPPED: Between 1–1–57 and 12–31–58, from Memphis, Tenn.

LABEL IN PART: (Btl.) Bi-Nor-Ex Junior Multiple Vitamin and Mineral Elixir For Children * * * For infants * * * For Adults too!! * * * Distributed by Bilnor Distributors, Inc.—Detroit (One Average Teaspoonful (5 cc.) contains: * * * Vitamin C 30 mgms."

ACCOMPANYING LABELING: Carton insert entitled "At Last . . . Bi-Nor-Ex The Balanced Multiple Vitamin and Mineral Food Supplement That Provides 37 Vital Food Factors For You!"

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 7 percent of the declared amount of vitamin C. The article had been manufactured on order of the dealer; shipped in bulk lots; then repacked by the dealer into the above bottles. The carton inserts had been prepared on order of the dealer.

LIBELED: 7–15–63, E. Dist. Mich.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "One Average Teaspoonful (5 cc.) contains: * * * Vitamin C 30 mgms." was false and misleading as applied to a product containing less vitamin C; and 502(a)—the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of gray hair at an early age, decay and loss of teeth, lusterless eyes, lessened ability to work, failing memory, deadened ears, listlessness, irritable disposition, nervousness, and tiredness; to promote robust good health, strong bones and teeth, reproductive efficiency, intelligence, pep, enthusiasm, and energy; resistance against disease, colds, and infections; health, and growth; that it was a balanced food supplement; that 75 percent of the foods generally available were devitalized, demineralized, and devitaminized, and cannot supply all of the elements needed for good health; and that every ounce of sugar consumed reduces the ability to resist infection; that millions of people are starving from hidden hunger; and that 7 out of 10 Americans are suffering from malnutrition.

DISPOSITION: 9–5–63. Default—destruction.

7924. Aspirin tablets. (F.D.C. No. 48587. S. No. 42–747 V.)

QUANTITY: 182 1,000-tablet btls. at Philadelphia, Pa.

SHIPPED: 10–16–62, from Brooklyn, N.Y., by Bolar Pharmaceutical Co., Inc.

LABEL IN PART: (Btl.) "1000 Aspirin 5 grains * * * Distributed by Miller Drug Co. Philadelphia, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 90 percent of the declared amount of acetylsalicylic acid.

LIBELED: 1–8–63, E. Dist. Pa.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, "Aspirin Tablets," the name of which was recognized in the United States Pharmacopeia, and its strength differed from and its quality fell below the standard set forth in such compendium.

DISPOSITION: 2–6–63. Default—destruction.

7925. Rubber prophylactics. (F.D.C. No. 49254. S. No. 4–519 X.)

QUANTITY: 198 ctns., each containing 12 3-units boxes, at Baltimore, Md.

SHIPPED: 8–19–63, from Akron, Ohio, by Akwell Corp.

LABEL IN PART: (Box & pkg.) "The Chief Super Thin Prophylactics* * * Lee-Mor Products Co., Baltimore 1, Md."

RESULTS OF INVESTIGATION: Examination showed that approximately 2 percent of the article contained holes.

LIBELED: 9–9–63, Dist. Md.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements, (box) "Sold

for prevention of disease only" and (unit pkg.) "Disease Preventatives," were false and misleading as applied to a product containing holes.

DISPOSITION: 10–3–63. Default—destruction.

7926. Rubber prophylactics. (F.D.C. No. 48751. S. No. 87–576 V.)

QUANTITY: 50 ctns., each containing 72 2-unit pkgs., at St. Louis, Mo.

SHIPPED: Prior to 3–14–63, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Pkg.) "Spartans Prophylactics * * * M & M Rubber Co., Kansas City 8, Mo.* * * Sold for Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination of 188 units showed that 1.5 percent were defective in that they contained holes.

LIBELED: 5–17–63, E. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality fell below that which it was purported to possess; and 502(a)—the label statement "Sold for Prevention of Disease Only" was false and misleading.

DISPOSITION: 7–29–63. Default—destruction.

7927. Rubber prophylactics. (F.D.C. No. 48287. S. No. 18–088 V.)

QUANTITY: 28 ctns., each containing 48 3-unit boxes, at Houston, Tex.

SHIPPED: 10–15–62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Box) "Dean's Peacocks * * * An aid in preventing venereal diseases. The Dean Rubber Mfg. Company North Kansas City, Mo."

RESULTS OF INVESTIGATION: Examination showed that 1.3 percent of the units tested were defective.

LIBELED: 11–9–62, S. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "An aid in preventing venereal disease" was false and misleading.

DISPOSITION: 12–13–62. Default—destruction.

DRUGS FOR VETERINARY USE*

7928. Medicated Stress Granules. (F.D.C. No. 48787. S. No. 54–272 V.)

QUANTITY: 100 50-lb. bags at Sioux City, Iowa.

SHIPPED: 12–26–62, from Crete, Nebr., by Lauhoff Grain Co.

LABEL IN PART: (Bag) "Victor Medicated Stress Granules * * * Active Drugs Ingredient Furazolidone 0.011 Percent * * * Manufactured by the Crete Mills Division of Lauhoff Grain Company, Crete, Nebraska."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of furazolidone.

LIBELED: 5–23–63, N. Dist. Iowa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Furazolidone 0.011 Percent" was false and misleading, and its label also contained false and misleading representations that the article was adequate and effective for the prevention of blackhead (enterohepatitis) in chickens and turkeys, hexamitiasis in turkeys, and for the treatment of Salmonella diseases (typhoid,

*See also No. 7919.

the paratyphoids, and pullorum), synovitis, chronic respiratory diseases (air-sac infection), nonspecific enteritis (blue comb and mud fever), and quail disease (ulcerative enteritis) in chickens and turkeys.

DISPOSITION: 6–28–63. Default—destruction.

7929. Alfalfa pellets. (F.D.C. No. 48801. S. No. 52–223 V.)

QUANTITY: 109 100-lb. bags at Laurel, Mont.

SHIPPED: 11–12–62, from La Salle, Colo., by John Ewing Co.

LABEL IN PART: "John Ewing Company Diethylstilbestrol Mix Incorporated In Dehydrated Alfalfa Pellets for Fattening Beef Cattle Active Drug Ingredient Diethylstilbestrol .0022% * * * Manufactured by John Ewing Company La Salle, Colorado."

LIBELED: 3–8–63, Dist. Mont.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Diethylstilbestrol .0022%" was false and misleading.

DISPOSITION: 4–8–63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7930. Formula B–13. (F.D.C. No. 46017. S. No. 48–621 P.) *See also* D.D.N.J. No. 7202.

INFORMATION FILED: 9–7–61, Dist. N. Mex., against Emmett F. Stockton, t/a Stockton Laboratories, and Co., Albuquerque, N. Mex.

SHIPPED: 3–18–59, from Albuquerque, N. Mex., to Berkeley, Calif.

LABEL IN PART: (Btl.) "FORMULA B–13 Two Pulvules Contain: Special Liver-Stomach Concentrate (Containing Intrinsic Factor) 300 Mg. Vitamin B–12 with Intrinsic Factor Concentrate, U.S.P.–1–U.S.P. Unit (Oral) Vitamin B–12 Activity Concentrate, N.F. 15 Mcg. The above Ingredients are Clinically Equivalent to 1½ U.S.P. Units of A.P.A. Potency: Ferrous Sulfate, Anhydrous 600 Mg. Equal to over 1 Gm. Ferrous Sulfate, U.S.P. Ascorbic Acid (Vitamin C) 150 Mg. Folic Acid 2 Mg. 60 Capsules Obtained from extractives of suitable microbial organisms and liver and determined microbiologically against vitamin B–12 standard, the total amount, including that contained in the Vitamin B–12 with intrinsic factor concentrate. U.S.P. is 30 Micrograms. Usual Adult Dose * * * STOCKTON LABORATORIES, AND CO. * * * Albuquerque, New Mexico."

ACCOMPANYING LABELING: Undated form letter entitled "Subject: ULCERS" and a letter dated March 17, 1959, bearing the letterhead "The Stockton Laboratories, and Co." and signed by G. T. Graham.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the drug was adequate and effective in the treatment of duodenal and gastric ulcers.

PLEA: Guilty.

DISPOSITION: 12–8–61. Probation for 2 years.

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*See also Nos. 7881, 7884, 7885, 7888, 7894, 7896–7898, 7901–7903, 7905–7909, 7914, 7915, 7920–7923, 7925–7927.

7931. Regimen tablets (12 seizure actions). (F.D.C. Nos. 49707, 49708, 49710, 49718, 49721, 49722, 49738, 49928, 49933, 49944, 50084, 50086. S. Nos. 13–661 A; 13–662 A; 13–663 A; 12–423 A; 12–422 A; 12–421 A; 85–265/6 A; 13–856 A; 2–498/9 A; 35–008/9 A; 66–865 A; 19–917 A.)

QUANTITY: 509 78-tablet boxes and 278 156-tablet boxes at Boston, Mass.; 223 78-tablet boxes and 14 156-tablet boxes at Lynn, Mass.; 288 78-tablet boxes at Lynn, Mass.; 124 78-tablet boxes at Lawrence, Mass.; 100 78-tablet boxes and 5 156-tablet boxes at Randolph, Mass.; 265 78-tablet boxes and 56 156-tablet boxes at Canton, Mass.; 37 156-tablet boxes and 466 78-tablet boxes at Philadelphia, Pa.; 78 156-tablet boxes and 286 78-tablet boxes at Malden, Mass.; 74 78-tablet boxes and 17 156-tablet boxes at Charlotte, N.C.; 23 156-tablet boxes and 83 78-tablet boxes at Bristol, Tenn.; 91 78-tablet boxes and 47 156-tablet boxes at Minneapolis, Minn.; and 196 78-tablet boxes and 145 156-tablet boxes at Sharpsburg, Pa.

SHIPPED: Between 11–9–61 and 9–6–63, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen-Tablets * * * contain:—(In Green tablets) Vitamin D (irradiated yeast), B_1, B_2, B_6, and C, Niacinamide, Calcium Pantethenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride, Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Ammonium Chloride. * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular in box reading in part "Reduce with the Regimen Plan A New Dietary Combination to Satisfy Hunger Remove Excess Water Control and Inhibit Appetite Drug Research Corp. New York, New York * * * As Long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss."

LIBELED: 1–7–64, Dist. Mass.; 1–10–64, Dist. Mass.; 1–10–64, Dist. Mass.; 1–14–64, Dist. Mass.; 1–14–64, Dist. Mass.; 1–14–64, Dist. Mass.; 1–22–64, E. Dist. Pa.; 3–16–64, Dist. Mass.; 3–24–64, W. Dist. N.C.; 3–31–64, E. Dist. Tenn.; 5–11–64, Dist. Minn.; and 5–12–64, W. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen plan" could do most everything medical science could do to help one attain one's goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were more susceptible to cancer.

DISPOSITION: 2–25–64; 6–30–64; 6–30–64; 2–28–64; 2–28–64; 2–28–64; 8–4–64; 6–30–64; 6–10–64; 5–27–64; 6–23–64; and 6–9–64. Default—destruction.

7932. Regimen tablets (12 seizure actions). (F.D.C. Nos. 49734, 49743, 49745, 49756, 49761, 49772, 49784, 49786, 49879, 49881, 49897, 50102. S. Nos. 30–104 A; 49–942 A; 31–401/2 A; 30–305 A; 43–609 A; 43–803/4 A, 44–203/4 A; 69–884/5 A, 69–928 A; 84–304 A; 85–648/9 A; 84–305/6 A; 96–441 A; 1–197 A.)

QUANTITY: 126 78-tablet boxes at Indianapolis, Ind.; 250 78-tablet boxes at Detroit, Mich.; 46 78-tablet boxes and 12 156-tablet boxes at Paducah, Ky.;

34 78-tablet boxes and 15 156-tablet boxes at Nashville, Tenn.; 70 78-tablet boxes and 32 156-tablet boxes at Pueblo, Colo. 1,146 78-tablet boxes and 377 156-tablet boxes at Denver, Colo.; 108 78-tablet boxes and 160 156-tablet boxes at St. Paul, Minn., and 195 78-tablet boxes and 52 156-tablet boxes at Minneapolis, Minn.; 133 78-tablet boxes and 19 156-tablet boxes at St. Louis, Mo.; 101 78-tablet boxes and 7 156-tablet boxes at Wilkes-Barre, Pa.; 5 cases, each containing 72 78-tablet boxes and 96 78-tablet boxes, and 6 cases, each containing 36 156-tablet boxes and 32 156-tablet boxes, at St. Louis, Mo.; 33 78-tablet boxes and 94 156-tablet boxes at Oakland, Calif.; and 309 78-tablet boxes at Atlanta, Ga.

SHIPPED: Between 12–18–62 and 1–2–64, from Long Island City, N.Y., and New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen-Tablets * * * contain: (In Green tablets) Vitamin D (irradiated yeast), B_1, B_2, B_6 and C, Niacinamide, Calcium Pantethenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride, Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Ammonium Chloride. * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circulars entitled "Reduce with the Regimen Plan: A New Dietary Combination to Satisfy Hunger Remove Excess Water Control and Inhibit Appetite Drug Research Corp. New York, New York * * * As Long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss."

LIBELED: 1–27–64, S. Dist. Ind.; 1–28–64, E. Dist. Mich.; 1–28–64, W. Dist. Ky.; 1–30–64, M. Dist. Tenn.; 2–4–64, Dist. Colo.; 2–6–64, Dist. Colo.; 2–13–64, 2–14–64, Dist. Minn.; 2–19–64, E. Dist. Mo.; 2–18–64, M. Dist. Pa.; 2–19–64, E. Dist. Mo.; 3–2–64, N. Dist. Calif.; 4–30–64, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen plan" could do most everything medical science could do to help one attain one's goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were more susceptible to cancer.

DISPOSITION: 3–12–64; 4–20–64; 3–19–64; 3–20–64; 4–1–64; 4–6–64; 4–1–64; 4–24–64; 3–18–64; 4–24–64; 4–17–64; 6–12–64. Default—destruction.

7933. Various vitamin preparations. (F.D.C. No. 44376. S. Nos. 96–867/71 P.)

QUANTITY: 1 bulk can of 12,000 capsules and 11 100-capsule btls., 13 200-capsule btls., 2 100-capsule btls., and 5 200-capsule btls., of *vitamins A and D;* 1 bulk container of 20,000 capsules, 34 100-capsule btls., 39 200-capsule btls., and 4 500-capsule btls., of *Natural B Complex;* 22 ctns., 12 4-oz. btls. each, and 4 4-oz. btls. of *brewers yeast;* 122 100-tablet btls., 109 200-tablet btls., of *Geriatric Gelly,* at New York, N.Y., in possession of Charles Falkner, Inc., and in possession of the same firm, t/a Sunny-Health Foods.

SHIPPED: Between 4–30–57 and 1–12–60, (*Natural B Complex* and *Geriatric Gelly*) from Hoboken, N.J., by Willow Pharmacal Corp., and (other above-named articles) from Worcester, Mass.

LABELS IN PART: (Btl.) "Falkner's 'Aydee' Formula Natural Vitamin A and D Capsules (from fish liver lipoids) In A Base of Pure Wheat Germ Oil Each Capsule provides: * * * Charles Falkner, Inc. Distr. New York 21, N.Y."; (btl.) "Falkner's Natural B Complex with Vitamin B–12 (2 mcg. Vitamin B–12 per capsule) Each capsule contains * * * Plus 2 mcg. of Vitamin B_{12} per capsule for which Need in Human Nutrition has not yet been established. * * * Charles Falkner, Inc. Distr.–New York 21, N.Y."; (btl.) "Falkner's Super All-Natural B Concentrate (Brewers Yeast) Each teaspoonful contains the unknown as well as the known B-Complex Vitamins Found in 17.5 Gm. or more of Brewers Yeast"; (btl.) "Falkner's Royal Geriatric Gelly An All-Natural High Potency Vitamin and Mineral With Addition of Royal Jelly 3307 Distributed by Charles Falkner, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Falkner's Special Holiday Sale," "The Gift of Good Health," and "Falkner's Special Spring Sale"; and a number of bottle labels for *vitamin A and D capsules* and *Natural B Complex capsules.*

RESULTS OF INVESTIGATION: The *Vitaman A and D capsules* and *Natural B Complex capsules* in the bottles were repacked from bulk containers shipped as described above.

LIBELED: 3–25–60, S. Dist. N.Y.

CHARGE: *Vitamin A and D capsules*, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment of low resistance, infections, and to replenish strength; and for resistance of nasal, sinus, and respiratory tissues to bacterial invasion.

Natural B Complex capsules, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for and preventive of weak, tired, run-down conditions; nervous, irritable, easily irked conditions; and inability to concentrate.

Brewers yeast, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was an adequate treatment for and preventive of loss of mental or physical power; loss of energy and zest for living; depression; irritability; and inability to concentrate.

Geriatric Gelly, 502(a)—when shipped and while held for sale, the name of the article and the accompanying labeling contained false and misleading representations that the article would increase the life span and promote youth and strength in people of old age.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 9–15–60. Consent—claimed by Charles Falkner, Inc., and relabeled.

7934. Golden-50 Tabulets. (F.D.C. No. 48958. S. No. 65–574 V.)

QUANTITY: 86 ctns., each containing 108 30-tablet btls., at New York, N.Y.

SHIPPED: 12–20–62, from Chicago, Ill., by Savoy Drug & Chemical Co.

LABEL IN PART: (Btl.) "Golden-50 Tabulets A high potency vitamin and mineral food supplement with digestive enzymes distributed by Golden 50 Pharmaceutical Co. * * * New York, 10, N.Y. * * *

Each Tabulet Contains: Vitamin A (Acetate) 15,000 USP Units Vitamin D (Irr-ergosterol) 1,000 INT. Units Vitamin B_1 (Mononitrate) 15 mg. Vitamin B_2 (Riboflavin) 6 mg. Vitamin B_6 (Pyridoxine HCL) 1 mg. Vitamin B_{12} (Cyanocobalamine) 5 meg. Vitamin C (Ascorbic Acid) 100 mg. Niacinamide 50 mg. Vitamin E (Succinate) 10 INT. Pancreatic Enzyme (Con) 125 mg. Calcium Pantothenate 7 mg. Lemon Bioflavonoid (Complex) 25 mg. Inositol 15 mg. Choline Bitartrate 15 mg. dl Methionine 15 mg. Rutin 25 mg. Biotin 30 mcg. Betain (HCL) 10 mg. Para Amino Benzoic Acid 10 mg. Iron (Sulfate) 20 mg. Calcium (Di-Cal-Phos) 30 mg. Phosphorus (Di-Cal-Phos) 25 mg. Sodium Chloride 1 mg. Iodine (K I) 0.15 mg. Sulfur (Sulfates) 15 mg. Potassium (Sulfate) 5 mg. Aluminum Hydroxide 30 mg. Magnesium (Sulfate) 4 mg. Copper (Sulfate) 0.6 mg. Manganese (Sulfate) 0.6 mg. Zinc (Sulfate) 1.0 mg."

ACCOMPANYING LABELING: 150 booklets entitled "Facts You Should Know When You are Over 50"; 50 testimonial letters headed "Yours free 30 day Supply of High Potency Vitamins"; 4,500 "Dear Friend" letters beginning "Important, Please Read"; 4,000 "Dear Friend" letters beginning "Congratulations!"; and undetermined quantities of a leaflet entitled "Free Gift Check."

LIBELED: On or about 5–20–63, S. Dist. N.Y.

CHARGE: 502(a)—When shipped and while held for sale, the labeling including the name "*Golden-50*" contained false and misleading representations that the article was adequate and effective for the treatment and prevention of run-down and weak conditions; lack of energy; inability to withstand the noise of children; tiredness; lack of pep in the morning and night; conditions due to worry; lack of appetite; loss of enjoyment of life; inability to be the man or woman formerly possible; coated tongue; bleeding gums; tooth decay; brittle bones; constipation; weight loss; poor eyesight; inability to sleep; skin breaking out; nervousness; bad digestion; gas; heart conditions; swollen, inflamed joints; mental depression; and to promote strength; "get up and go"; pep; stamina; happy, healthy living; fullness of life far into the middle years; to feel young and to retard aging; and that the nutritional requirements of people past 50 were different from adults generally; that the pancreatic enzymes in the article would promote proper digestion of foods; and that all the ingredients in the article were nutritionally significant vitamins and minerals.

DISPOSITION: 4–17–64. Default—destruction.

7935. Sea and Ski cream. (F.D.C. No. 45376. S. No. 19–138 R.)

QUANTITY: 204 individually ctnd. 2-oz. tubes and 276 individually ctnd. 4-oz. tubes, at Denver, Colo.

SHIPPED: 5–25–60 and 6–14–60, from Reno, Nev., by Rolley Co. (Div. of Botany Industries, Inc.).

LABEL IN PART: (Tube) "Sea and Ski Tanning Cream * * * Rolley Co., So. San Francisco, California."

RESULTS OF INVESTIGATION: Analysis showed the article to be a light green, perfumed, oil-in-water cream containing glyceryl p-aminobenzoate, hydrocarbons, fatty acids, triethanolamine soap, glycerin, talc, and esters which include lanolin and/or sterols.

LIBELED: 12–29–60, Dist. Colo.

CHARGE: 502(a)—when shipped, the carton and tube labels contained false and misleading representations that the article would positively prevent sunburn and peeling; heal household burns, correct teen-age acne; relieve stings of insect bites; and heal poison oak; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active drug ingredient.

DISPOSITION: On 3–21–61, Botany Industries, Inc., filed a claim to the article; and pursuant to stipulation, the case was removed to the Eastern District of Pennsylvania. On 3–27–63, a consent decree of condemnation was entered, which decree stated that the claimant did not admit the allegations of the libel and denied that the article was misbranded but, for settlement purposes only, the claimant consented that such decree be entered condemning the article under seizure. Thereafter, the article having been adjudged to be misbranded, the article was destroyed.

7936. Lovelite facial pack. (F.D.C. No. 49345. S. No. 49–454 X.)

QUANTITY: 816 2-oz. jars at Fresno, Calif.

SHIPPED: Prior to 7–25–63, from Las Vegas, Nev., by Lovelite Cosmetics, Inc.

LABEL IN PART: (Jar) "Lovelite Facial Pack * * * Lovelite Cosmetics, Inc. Las Vegas, Nevada."

ACCOMPANYING LABELING: Booklet entitled "Lovelite Cosmetics Are Designed to Make You More Beautiful."

RESULTS OF INVESTIGATION: Examination showed the article to consist of a yellow-white solid fatty substance.

LIBELED: 9–24–63, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective to aid in the reduction of minor skin disorders and blemishes; smooth out tired lines and wrinkles; and activate circulation; that "use of this medication as a facial treatment cannot be equalled in its efficiency"; and that "Lovelite Facial Pack aids in healing skin irritations, blemishes, removal of blackheads, activates circulation, smooths out tired lines and wrinkles, makes your face feel fresh, firm, smooth and silky"; and 502(e)(1)(A)(ii)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: 11–7–63. Default—destruction.

7937. Safe-T-Sun Health-Tan sun lamp. (F.D.C. No. 49705. S. No. 44–646 X.)

QUANTITY: 522 ctns. containing the unassembled parts of an undetermined number of devices at Bridgeport, Pa.

SHIPPED: 10–9–63, from Toronto, Ontario, Canada, by Federal Discount Corp., Ltd.

LABEL IN PART: (Some ctns.) "Glass Sun Lamp Safe-T-Sun Corp. Williamsburg, Va."

ACCOMPANYING LABELING: Envelope reading in part "Assembly of Health Tan Sun Lamp * * * Operating Instructions"; and a folder reading in part "Yes! This is the amazing new Safe-T-Sun Health-Tan Sun Lamp That Can't Burn * * * the only truly safe sun lamp with built-in health benefits Catalina Model."

RESULTS OF INVESTIGATION: Investigation showed that some of the cartons contained the bases and telescoping upright poles of the devices, and that other

cartons contained lamp-socket-and-cord assemblies, bulbs, filters in an envelope, and the above-mentioned folders. Examination indicated that, when assembled, the article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: 1–8–64, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the article was adequate and effective for the treatment of adolescent and other skin problems, relieving tired back, arthritic and rheumatic-like pains, chills, stiff neck and back; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning and that infants could be exposed for hours without the slightest harm; and that the device could be used as a "sunlamp that can't burn."

DISPOSITION: 4–22–64. Default—destruction.

7938. Air purifier device. (F.D.C. No. 48062. S. No. 77–177 T.)

QUANTITY: 19 devices, at St. Petersburg, Fla., in possession of Vita-Aire Corp.

SHIPPED: 5–24–62, from Milwaukee, Wis.

LABEL IN PART: (Metal plates) "Vita-Aire Vitalized Oxygen" and "Negative Ionizer—Air Purifier * * * Model * * * Serial * * * Vita-Aire Corporation, Ft. Lauderdale, Fla."

ACCOMPANYING LABELING: Leaflet entitled "Vita-Aire Negative Ionizer Air Purifier."

RESULTS OF INVESTIGATION: Examination indicated the device to be an ultraviolet ozone generator containing a heating element and an air blower.

LIBELED: 8–23–62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article would generate negative ions using ultraviolet rays which would oxidize and destroy most airborne bacteria, provide relief from hay fever, asthma, and other uncomplicated respiratory conditions, and would eliminate unwanted airborne contamination.

DISPOSITION: 11–29–62. Consent—claimed by Vita-Aire Corp., of St. Petersburg, Pinellas County, Fla., and relabeled.

DRUGS FOR VETERINARY USE*

7939. Mineral Water Concentrate and Litter Iron. (F.D.C. No. 46755. S. Nos. 16–581/2 T.)

QUANTITY: 240 gals. in bbls., 5 1-gal. unlabeled btls., and 34 1-qt. btls., at Lexington, Ky., in possession of Hess Bros.

SHIPPED: 6–29–61 and 8–14–61, from Bay Springs, Miss.

LABEL IN PART: (Btl.) "Hess Bros. Mineral Water Concentrate * * * Contents One Gallon, Hess Bros., Lexington, Ky," and (Btl.) "Hess Bros. Litter Iron for Healthy Profit Making Pigs * * * Contents One Quart, Hess Bros., Lexington, Ky."

ACCOMPANYING LABELING: Leaflets entitled "Horses Such as Bally Ache," "The $100,000 Question!" and "Eliminate Your Anemia Problems For Only 6¢ A Pig"; placards reading in part "As Advertised On Bay Springs Mineral Water

*See also Nos. 7889–7891, 7919, 7928, 7929.

Concentrate"; "Turfland Farms" letterheads to Mr. Douglas W. Hess; and a number of labels for 1-gallon and 1-quart bottles.

RESULTS OF INVESTIGATION: The articles had been shipped in barrels as described above and had been repacked in part into 1-gallon bottles, which were to bear the 1-gallon bottle label described above, and into the 1-quart bottles bearing the above-mentioned 1-quart bottle label. The accompanying labeling was printed locally for Hess Bros.

Analysis showed that the article contained 50.67 grams of total solids and 8.6 grams of iron per 100 milligrams.

LIBELED: 11–30–61, E. Dist. Ky.

CHARGE: *Mineral Water Concentrate* (bulk and repack), 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for veterinary use in horses for promoting growth and bloom and brighter hair-coat; to settle down; to increase appetite; promote racing ability; for the treatment of bleeding, tetanus, anemia, dapples, extreme nervousness, loss of control of hind quarters, staggering and falling down; and that the article was a mineral tonic.

Litter Iron (repack), 502(a)—the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for veterinary use in pigs to increase litters; promote health; and for the treatment and prevention of anemia of litter pigs.

(Both articles), 502(a)—the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for human use for the treatment of tired blood, irregularity, arthritis, rheumatism, nervous tension, and fatigue.

DISPOSITION: On 12–20–61, Douglas W. Hess, t/a Hess Bros., claimant, filed an answer denying that the articles were misbranded. On 12–31–62, the Government filed written interrogatories. Thereafter, an order was entered setting the case down for hearing on 5–4–64, at which time no one appeared on claimant's behalf. A default decree of condemnation was entered on 5–4–64, which noted that the articles under seizure had already been destroyed.

7940. Rawleigh stock premix. (F.D.C. No. 49123. S. No. 11–849 V.)

QUANTITY: 18 cases, each containing 8 5-lb. bags, at Menands, N.Y.

SHIPPED: 2–20–63, from Freeport, Ill., by W. T. Rawleigh Co.

LABEL IN PART: (Tag) "Rawleigh Stock Premix * * * Ingredients: Corn Distillers' Dried Grains; Soybean Mill Feed; Soybean Meal; Wheat Germ Meal; Vitamin A Palmitate in Gelatin; D-Activated Plant Sterol; dl-Alpha Tocopheryl Acetate; Manganous Oxide; Ferrous Carbonate; Copper Oxide; Potassium Iodide; Cobalt Carbonate; Zinc Oxide; Calcium Stearate; Calcium Carbonate, * * * Instructions."

ACCOMPANYING LABELING: Feeding chart in each bag entitled "Ration Chart Direction Card No. 11"; and leaflet in each case entitled "Service Leaflet No. 15."

LIBELED: 7–30–63, N. Dist. N.Y.

CHARGE: 502(a)—when shipped, the "Service Leaflet No. 15" accompanying the article contained false and misleading representations that the article, when used as directed, was adequate and effective for the treatment and prevention of white-muscle disease of calves and "stiff lamb" disease.

DISPOSITION: 9–9–63. Default—destruction.

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[1] (7882, 7939) Seizure contested.
[2] (7897) Seizure contested. Injunction issued.

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[1] (7882, 7939) Seizure contested.
[2] (7897) Seizure contested. Injunction issued.
[3] (7886) Seizure contested; contains opinion of the court; motions for summary judgment filed.

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[1] (7882, 7939) Seizure contested.

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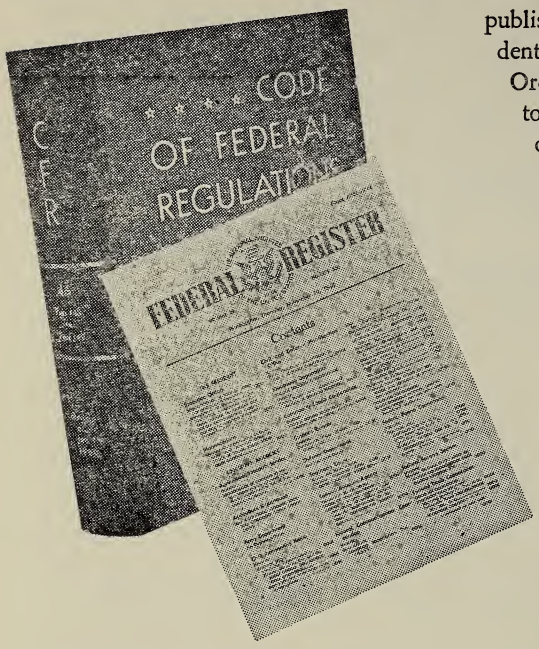

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D.D.N.J., F.D.C. 7941–8000 Issued May 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7941–8000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involved drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; in which, in one case, dismissal of the action was ordered after trial by the courts; and in which, in two cases, decrees of permanent injunction were also entered; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere; and, in one case, after trial by court and jury, upon a judgment of guilty, its partial affirmance and partial reversal upon appeal, and the denial of certiorari; (3) injunction proceedings in which decrees of permanent injunction were issued after consent or after trial by the court; and (4) a criminal contempt proceeding which was terminated after trial by the court upon a judgment of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 28, 1965.*

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7941–8000

Adulteration, Section 501(a)(2), the article had been prepared, and packed under insanitary conditions whereby it may have been rendered injurious to health; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia) and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man, and it contained a quantity of a specified narcotic or hypnotic substance, or of a chemical derivative of such substance, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(e)(1)(A)(i), the article was a drug, and its label failed to bear the established name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, chlortetracycline, or bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(1), the article was a drug intended for use by man which was a habit-forming drug to which Section 502(d) applied, or because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, or was limited by an approved or effective application under Section 505, to use under the professional supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and

its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7941. Ferrous fumarate capsules, digitalis tablets, dextro-amphetamine sulfate and amobarbital tablets, Reducing Set Gray No. 1 tablets, Wil-O-Bex pink timed disintegration capsules, timed disintegration capsules, pentaerythritol tetranitrate tablets. (F.D.C. No. 49136. S. Nos. 18–083 T, 41–776/7 T, 44–527/8 T, 56–189/90 T, 73–500 T, 74–247 T.)

INFORMATION FILED: 11–19–63, Dist. N.J., against Kingston Laboratories, Ltd., Hoboken, N.J., Lyonel Berken, president, and John Gonzales, secretary.

SHIPPED: Between 7–25–61 and 7–6–62, from Hoboken, N.J., to Houston, Tex., Brooklyn, N.Y., Bellerose, N.Y., Philadelphia, Pa., and Buffalo, N.Y.

LABEL IN PART: (Drum) "Each Capsule Contains: Ferrous Fumarate – – – – 5 gr. Caution: Federal law prohibits dispensing without a prescription. KINGSTON LABORATORIES, LTD."; (can) "Paramount 5000 Tablets DIGITALIS Enteric Coated Each tablet contains: Digitalis USP 1½ (0.1 Gm.) Distributed By Paramount Surgical Supply Co. Brooklyn, N.Y."; (btl.) "1000 Tablets Dextro-Amphetamine Sulfate & Amobarbital Each tablet contains Dextro Amphetamine Sulfate 5 mgm. Amobarbital ½ gr. Warning: May be habit forming. Average Dose: 1 tablet Caution: Federal law prohibits dispensing without prescription. Distributed by Rugby Laboratories, Inc. Brooklyn, N.Y."; (ctn.) "W Tablets REDUCING SET GRAY No. 1 Each tablet contains: d–l Amphetamine Sulfate 10 Mg. Thyroid U.S.P. 1 gr. Atropine Sulfate 1/360 gr. Aloin ¼ gr. Caution * * * Warning * * * Kingston Laboratories Ltd. Hoboken. N.J."; (box) "WIL-O-BEX * * * Timed Disintegration Capsule Each Capsule Contains: D.L. Amphetamine Sulfate 30 mg. Thyroid 3 gr. Atropine Sulfate 1/180 gr. Aloin ¼ gr. Phenobarbital ¼ gr. * * * Warning: * * * Caution * * * Kingston Laboratories, Ltd. Hoboken, N.J."; and "TIMED DISINTEGRATION CAPSULE D.L. Amphetamine Sulfate 30 mg. Thyroid 3 gr. Atropine Sulfate 1/180 gr. Aloin ¼ gr. Phenobarbital ¼ gr. Warning * * * Caution * * * Distributed by RUGBY LABORATORIES, INC. Brooklyn, N.Y."

CHARGE: *Ferrous fumarate capsules*, 501(c)—when shipped, the strength of the article differed from that which it purported to possess in that each capsule contained less than 5 gr.; and 502(a)—the label statement "Each capsule contains Ferrous Fumarate – – – – 5 gr." was false and misleading.

Digitalis tablets, 501(b)—when shipped, the strength of the article fell below the standard for *digitalis tablets*, set forth in the United States Pharmacopeia, since the article contained less than the labeled amount of powdered digitalis; and 502(a)—the label statement "Each tablet contains: Digitalis U.S.P. 1½ (0.1 gm.)" was false and misleading.

Dextro-amphetamine sulfate and amobarbital tablets, 501(a)(2)—when shipped, the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; and 501(c)—the purity and quality of the article fell below that which it purported to possess since it contained lindane.

Reducing Set Gray No. 1 tablets, 501(a)(2)—the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; and 501(c)—the purity and quality of the article fell below that which it purported to possess since it contained lindane.

Wil-O-Bex pink timed disintegration capsules, 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

Wil-O-Bex pink timed disintegration capsules, 501(c)—when shipped, the purity and quality of the article fell below that which it purported to possess since the contents of each capsule would not disintegrate at a uniform rate throughout a 6- to 10-hour period; and 502(a)—the labeling contained false and misleading representations that the contents of each capsule would disintegrate at a uniform rate throughout a 6- to 10-hour period.

Timed disintegration capsules, 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to law was not effective with respect to such drug; 501(c)—when shipped, the quality of the article fell below that which it purported to possess since the contents of each capsule would not disintegrate at a uniform rate throughout a 6- to 10-hour period; and 502(a)—the labeling contained false and misleading representations that the contents of each capsule would disintegrate at a uniform rate throughout a 6- to 10-hour period.

Pentaerythritol tetranitrate tablets, 501(a)(2)—when shipped, the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; and 501(c)—the purity and quality of the article fell below that which it purported to possess since it contained lindane.

PLEA: Guilty by the corporation to 16 counts; guilty by the individuals to 2 counts.

DISPOSITION: 7–22–64. Corporation—sentence of 1 year in prison, with all books and records to be in the custody of the probation officer for 1 year; Berken—probation for 3 years; Gonzales—1 year in prison suspended, and probation for 5 years.

7942. Paratrine. (F.D.C. No. 49760. S. No. 39–985 A.)

QUANTITY: 49 ctns., each containing 12 1-cc. ampuls, and 17 ctns., each containing 100 1-cc. ampuls, at San Antonio, Tex., in possession of Knight Pharmacal Co.

SHIPPED: 10–17–63, from Chicago, Ill., by Maizel Laboratories, Inc.

LABEL IN PART: (Ctn.) "Paratrine * * * Each cc. contains: Sparteine Sulfate 150 mg.; water for injection q.s. Intramuscular Only Dose: * * * Indications: * * * Contraindications: * * * Distributed by Bexar Pharmaceuticals, Inc., San Antonio, Texas" and (ampul) "Paratrine 150 mg. * * * Bexar Pharm. Inc. San Antonio, Texas."

ACCOMPANYING LABELING: Physician reference cards reading in part "Paratrine (For Uterine Inertia) Composition: * * * Bexar Pharmaceutical's brand of sparteine sulfate. Each ampul contains 150 mgs. of sparteine sulfate dissolved in 1 cc. of 0.45% saline. * * * Bexar Pharmaceuticals Inc., San Antonio, Texas."

LIBELED: 1–31–64, W. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drug; 502(e)(1)(A)(i)—when shipped, the ampul label failed to bear the established name, sparteine sulfate; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes; and 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article had advantages over other oxytocic agents; that there had been no reports of violent or tetanic uterine contractions when used in recommended doses; that it did not require the rigid supervision of administration which is necessary with other oxytocics; and that no harmful effects on either the mother or the fetus had been reported even when used in amounts four times greater than those recommended.

DISPOSITION: 6–8–64. Consent—destruction.

7943. Strophanthin tablets. (F.D.C. No. 50310. S. Nos. 78–981/4 A, 79–617/20 A.)

QUANTITY: 2 drums, each containing 4,000 *No. 5½ tablets;* 2 drums, each containing 4,000 *No. 6 tablets*; 2 drums, each containing 4,000 *No. 6½ tablets;* 2 drums, each containing 4,000 tablets of *No. 10 Green;* 2 drums, each containing 4,000 *No. 1½ tablets;* 2 drums, each containing 4,000 *No. 2½ tablets;* 2 drums, each containing 4,000 *No. 3 tablets*; and 2 drums, each containing 4,000 *No. 5 tablets*, at Teaneck, N.J.

SHIPPED: 12–8–63, from Costa Mesa, Calif., by Cusicks.

LABEL IN PART: (Loose labels) "5040 Tablets No. 5½ Each Tablet Contains 3.24 mg. Strophanthin K, NFX Standardized to contain 2.67 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks P6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," "5040 Tablets No. 6 Each tablet contains: 0.81 mg. Strophanthin K, NFX Standardized to contain 2.92 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," "5040 Tablets No. 6½ Each tablet contains: 0.437 mg. Strophanthin K, NFX Standardized to contain 3.16 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," "#10 Green," "5040 Tablets No. 1½ Each tablet contains: 0.81 mg. Strophanthin K, NFX 97.2 mgs. Anterior Pituitary 1.5 mgs. Thiamine Hydrochloride Standarized to contain 0.73 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," "5040 Tablets No. 2½ Each tablet contains 0.675 mg. Strophanthin K, NFX Standardized to contain 1.22 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," "5040 Tablets No. 3 Each tablet contains: 0.405 mg. Strophanthin K, NFX Standardized to contain 1.36 m. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manu-

factured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," and "5040 Tablets No. 5 Each tablet contains: 1.35 mg. Strophanthin K, NFX Standardized to contain 2.43 mg. preformed thyroxine in Cusicks Iodinated Protein * * * Usual Dosage: * * * Manufactured by Cusicks Q6 Dept. Weight Therapy 'WT' Costa Mesa, Calif.," and all except "#10 Green" labeled further "Caution: New Drug—Limited by Federal Law to investigational use."

RESULTS OF INVESTIGATION: Factory inspection of the manufacturer showed that the *#10 Green tablets* had a formulation containing 2.7 mg. "Strophanthin K, NFX tablets" standardized to contain 4.86 mg. preformed thyroxine in Cusicks Iodinated Protein.

LIBELED: 6–25–64, Dist. N.J.

CHARGE: *Tablets Nos. 5½, 6, 6½, 1½, 2½, 3, and 5*, 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drugs.

#10 Green tablets, 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 8–13–64. Default—destruction.

7944. Timed disintegration capsules. (F.D.C. No. 48104. S. Nos. 56–189/90 T.)

QUANTITY: 21 1,000-capsule cans at Brooklyn, N.Y.

SHIPPED: Between 5–1–62 and 5–8–62, from Hoboken, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Can) "Timed Disintegration Capsule D. L. Amphetamine Sulfate 30 mg. Thyroid 3 gr. Atropine Sulfate $\frac{1}{180}$ gr. Aloin ¼ gr. Phenobarbital ¼ gr."

RESULTS OF INVESTIGATION: Examination showed that the article contained amphetamine sulfate, the active ingredient, which was substantially released within one hour rather than uniformly over a 6- to 10-hour period. The article was labeled by the shipper for the dealer.

LIBELED: 9–28–62, E. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess, in that it failed to disintegrate at a uniform rate over a 6- to 10-hour period; 502(a)—the label statement "Each capsule prepared in a special base to allow for the disintegration of the contents throughout a 6-10 hour period" was false and misleading as applied to a product which failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2–18–63. Default—destruction.

7945. Laetrile. (F.D.C. No. 49556. S. No. 37–510 X.)

QUANTITY: 27 1,000-mg. vials at New Orleans, La.

SHIPPED: 11–22–63, from Plattsburgh, N.Y., by A. Johnston.

LABEL IN PART: "Laetrile * * * Rx AB Cyanogenic Glucoside for experimental use by qualified investigators only. * * * The McNaughton Foundation, Montreal, Canada."

LIBELED: 12–9–63, E. Dist. La.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: On or about 1–14–64. Default—delivered to the Food and Drug Administration.

7946. Virac Rex solution (2 seizure actions). (F.D.C. No. 48586. S. Nos. 53–297/305 V.)

QUANTITY: 8 1-pt. btls., 20 individually ctnd. 4-oz. btls., and 1 case containing 6 1-gal. btls., 19 1-gal. btls., 9 individually ctnd. 4-oz. btls., 12 1-pt. btls., 4 1-gal. btls., and 21 1-pt. btls., at Seattle, Wash.; 2 1-gal. btls. at Tacoma, Wash.

SHIPPED: Between 12–18–61 and 11–30–62, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Solution Virac Rex * * * The Modern Iodine Broad Spectrum Microbicide * * * Ruson Laboratories, Inc., Portland 2, Oregon * * * Active Ingredients: Undecoylium Chloride Iodine 1.80% (Available elemental iodine-0.6%)."

LIBELED: On or about 1–4–63, and on 1–15–63, W. Dist. Wash.

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, and no approval of an application filed pursuant to section 505(b), as amended, was effective with respect to such drug.

DISPOSITION: 2–12–63; 2–21–63. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

7947. Hog Unitrate No. 2. (F.D.C. No. 49072. S. No. 93–829 V.)

QUANTITY: 44 50-lb. bags at Alma, Wis.

SHIPPED: 3–21–63, from Mankato, Minn., by United Chemical Manufacturing Co.

LABEL IN PART: (Tag) "United Chemical Hog Unitrate No. 2 * * * Active Drug Ingredients: Arsanilic Acid 0.05% * * * Ingredients * * * Penicillin, Oxytetracycline, Chlortetracycline, Bacitracin * * * Manufactured For United Chemical Mfg. Co. Mankato, Minnesota."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately .0029 percent arsanilic acid, and .05 percent 3-nitro-4-hydroxyphenylarsonic acid.

LIBELED: 6–10–63, W. Dist. Wis.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 501(d)(2)—3-nitro-4-hydroxyphenylarsonic acid had been substituted wholly or in part for arsanilic acid; 502(a)—the label statement "Arsanilic Acid 0.05%" was false and misleading; 502(e)(2)—the label of the article failed to bear the common or usual name of each ingredient; and 502(l)—the article was composed in part of penicillin, chlortetracycline, and bacitracin, and it was not from a batch with respect to

which a certificate or release was in effect, and it was not exempt from such requirement.

DISPOSITION: 7–17–63. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7948. Prescription drugs. (F.D.C. No. 48898. S. Nos. 68–822 R, 69–490 R, 12–948 T, 12–955 T.)

INFORMATION FILED: 7–18–63, N. Dist. Ill., against David Hillman, t/a David Hillman Prescription Pharmacy and Hillman Pharmaceutical Co., Chicago, Ill., and Paul T. Bayer, pharmacist.

ALLEGED VIOLATIONS: Between 6–21–61 and 11–2–61, while *Dexedrine Spansule capsules*, *Dexedrine Sulfate tablets*, and *Equanil tablets* were being held for sale after shipment in interstate commerce, *Dexedrine Spansule capsules* and *Equanil tablets* were each dispensed once by Hillman, and *Dexedrine Sulfate tablets* were dispensed once by Bayer, without a prescription.

On 8–1–61, Hillman shipped misbranded *pentobarbital sodium capsules* in an unlabeled box from Chicago, Ill., to West Allis, Wis.

CHARGE: *Dexedrine Spansule capsules*, *Dexedrine Sulfate tablets*, and *Equanil tablets*, 503(b)(1)—while held for sale, the articles were drugs, within the meaning of (Dexedrine) 503(b)(1)(B) or (Equanil) 503(b)(1)(C), and were dispensed without a prescription.

Pentobarbital sodium capsules, 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use; and 503(b)(1)—the article was a drug, within the meaning of 503(b)(1)(A), and was dispensed without a prescription.

PLEA: Nolo contendere by Hillman to 3 counts; by Bayer to 1 count.

DISPOSITION: 1–22–64. Hillman—$300 fine, plus costs; Bayer—$100 fine, plus costs.

7949. Amphetamine sulfate tablets. (F.D.C. No. 50028. S. Nos. 62–027/31 A, 62–034 A, 62–038 A.)

INFORMATION FILED: 4–30–64, S. Dist. Calif., against Richard Lee Langham, Los Angeles, Calif., Rudolph Cunnigan, a/k/a Rudolph Cunningham, and Sylvia Langham, a/k/a Sylvia Spanton.

ALLEGED VIOLATION: Between 1–25–64 and 3–11–64, *amphetamine sulfate tablets* were dispensed 6 times without a prescription. In addition, on 4–8–64, while a number of *amphetamine sulfate tablets* were being held for sale after shipment in interstate commerce, Richard Lee Langham caused a number of such tablets to be held for sale in a container without any labeling, which act resulted in such tablets being misbranded.

CHARGE: 503(b)(1)—while held for sale, the article was dispensed without any labeling and without a prescription from a practitioner licensed by law to administer the article; 503(b)(4)—at a time prior to dispensing, the article failed to have a label bearing the statement "Caution: Federal law prohibits dispensing without prescription"; 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of numerical count; 502(e)(1)—the article failed to have a label bearing the established name of the article and the established name and quantity of its active ingredient; and 502(f)—the article did not have labeling bearing

(1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

PLEA: Guilty by Cunnigan and Sylvia Langham to 1 and 2 counts, respectively, involving the dispensing of the article; by Richard Langham to 4 counts involving the dispensing of the article and to 1 count involving the holding for sale of the article.

DISPOSITION: 9–8–64. Richard Lee Langham—4 years' imprisonment; Sylvia Langham—2 years' imprisonment; and Rudolph Cunnigan—1 year imprisonment.

7950. Nembutal Sodium capsules and Seconal Sodium capsules. (F.D.C. No. 49686. S. Nos. 27–105 X, 27–107 X, 27–109 X, 27–112 X.)

INDICTMENT RETURNED: 4–29–64, N. Dist. Iowa, against Sidney D. Smith, M.D., Waterloo, Iowa.

ALLEGED VIOLATION: On 7–3–63, the defendant caused the shipment from Waterloo, Iowa, to Kansas City, Kans., of an unlabeled box containing a number of misbranded *Seconal Sodium capsules.*

Between 6–24–63 and 7–3–63, *Nembutal Sodium capsules* were dispensed 3 times and *Seconal Sodium capsules* were dispensed once without a prescription.

CHARGE: *Seconal Sodium capsules,* 502(e)(1)—when shipped, the article failed to bear a label containing the common or usual name of the drug; 502(f)—the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users; and 503(b)(4)—the labeling of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Nembutal Sodium capsules and *Seconal Sodium capsules,* 503(b)(1)—while held for sale, the articles were drugs within the meaning of 503(b)(1)(A), and were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 6–2–64. A 1-year prison sentence suspended and placed on probation for 3 years.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7951. Amphetamine sulfate tablets. (F.D.C. No. 49995. S. Nos. 62–038/40 A.)

QUANTITY: 60,000 tablets, at Santa Monica and Los Angeles, Calif., in possession of Richard Lee Langham and Sylvia Langham.

SHIPPED: Prior to 4–8–64, from outside the State of California.

LIBELED: 4–16–64, S. Dist. Calif.

CHARGE: 503(b)(4)—while held for sale, the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of numerical count; 502(e)(1)—the article failed to have a label bearing

*See also Nos. 7949, 7950.

the established name of the drug and the established name and quantity of its active ingredient; and 502(f)—the labeling of the article failed to bear (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions where its use might be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: 5–19–64. Default—delivered to the Food and Drug Administration.

7952. Amphetamine sulfate tablets and capsules. (F.D.C. No. 47909. S. Nos. 94–703 T, 94–720 T.)

QUANTITY: 108,000 *amphetamine sulfate tablets and capsules* at Springfield, Mo., in possession of Ronald V. Mink.

SHIPPED: Prior to 6–27–62, from outside the State of Missouri.

LIBELED: On or about 8–31–62, W. Dist. Mo.

CHARGE: 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; 502(e)(1)—the article was a drug, and it was not designated solely by a name recognized in an official compendium and its label failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement since it was in the possession of persons who were not regularly or lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since such article was not to be dispensed as required by regulations; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the mandatory statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–17–62. Default—destruction.

7953. Various prescription drugs. (F.D.C. No. 48628. S. Nos. 26–362 V, 26–378/84 V.)

QUANTITY: Approximately 60 vials and btls. at St. Clair Shores, Mich., in possession of Lakeshore Drugs.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample" and "Physician Sample—not to be sold."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer, from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Michigan, with some labels bearing the words "Professional Sample" or similar wording, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Michigan; and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and bearing brand names indicative of manufacture outside the State of Michigan, and the names and addresses of manufacturers, packers, or distributors located outside the State of Michigan.

LIBELED: 3–6–63, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the sample legends on the labels of a number of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(e)—some of the articles failed to bear a label containing (1) the common or usual name of the drug, and (2) the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations; 503(b)(4)—a number of the articles were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; 502(d)—a number of the articles were drugs intended for use by man and contained a quantity of a narcotic or hypnotic substance, designated by 502(d), or a chemical derivative of such narcotic or hypnotic substance designated by regulations as habit forming, such as phenobarbital, and their labels failed to bear the statement "Warning—May be habit forming"; 502(a)—the statement "Equanil 400 mg." appearing on the labels of a number of the articles was false and misleading in that it represented and suggested that the articles consisted wholly of Equanil tablets, whereas the articles consisted in part of Miltown tablets; and 501(d)(2)—in a number of the articles labeled "Equanil," Miltown tablets had been substituted in part for Equanil tablets.

DISPOSITION: 6–11–63. Default—destruction.

7954. Safflower oil capsules and vitamin and mineral formula capsules. (F.D.C. No. 49617. S. Nos. 27–264/5 X.)

QUANTITY: 16 84-capsule btls. and 71 42-capsule btls., of *safflower oil capsules*, and 24 100-capsule btls., of *vitamin and mineral formula capsules*, at Lincoln, Nebr.

SHIPPED: Between 4–13–62 and 10–2–63, from Newark, N.J., by Welton Laboratories, Inc.

LABEL IN PART: (Btl.) "Welton Safflower Oil With Vitamin B–6 A dietary Supplement For Use With The Slim-Wel Reducing Program Packaged by Welton Laboratories, Inc. Newark 4, New Jersey Each Capsule Contains: Safflower Oil 912 mg. Vitamin B_6 * * * 0.5 mg. * * * Directions" and "Welton Therapeutic Vitamin and Mineral Formula A therapeutic formula intended for the treatment of essential vitamin and mineral deficiencies packaged by Welton Laboratories, Inc. Newark, N.J. * * * Dose: * * * Each Capsule Contains: * * * Vitamin K (menadione) 1 mg."

ACCOMPANYING LABELING: Booklets entitled "Slim-Wel Diet Guide and Safflower Oil Story Welton Laboratories, Inc."

LIBELED: 12–3–63, Dist. Nebr.

CHARGE: *Safflower oil capsules*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence therein of safflower oil, and that the article was adequate and effective to reduce and to control weight even though consuming thousands of calories daily

without regard to the total caloric intake, and to lower cholesterol levels of the blood.

Vitamin and mineral formula capsules, 503(b)(4)—when shipped, the article contained menadione and was a drug subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–28–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

7955. Millrue tonic. (F.D.C. No. 45197. S. Nos. 98–239/40 P, 38–946 R, 39–433 R, 41–569 R.)

INDICTMENT RETURNED: 4–5–61, S. Dist. Ill., against Millpax, Inc., Carlock, Ill., and Roy F. Paxton, secretary-treasurer.

ALLEGED SHIPMENTS: Between 11–4–59 and 5–23–60, from Carlock, Ill., to Muscatine, Iowa (counts 1 and 2), to Memphis, Tenn. (counts 3 and 4), and to San Francisco, Calif. (count 5).

LABEL IN PART: (Btl.) "MILLRUE Iron Tonic Hematinic Stomachic * * * Each fluid ounce supplies: Mallow Herb (water extractives) 5.6 Gm. (60 gr.) Ferric Ammonium Citrate 4.95 gr. Vitamin B_1 (Thiamin Hydrochloride) 5.69 mg. Vitamin B_2 (Riboflavin) 3.14 mg. Niacinamide 15 mg. Contents 8 Fl. Oz. * * * Manufactured by Millpax, Inc. Carlock, Illinois."

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which the article was intended, namely, (count 1) the treatment of diabetes, high blood pressure and ulcers of the stomach, (count 2) the treatment of arthritis, diabetes, tumor of the breast, and cancer, (counts 3 and 4) the treatment of cancer, (count 5) the treatment of stomach pains, constipation and cancer.

PLEA: Not guilty.

DISPOSITION: On 5–10–61, the defendants served a motion for discovery and inspection upon the Government. On 10–2–61, the defendants' motion was heard by the court, and thereafter, pursuant to order of the court, the Government furnished the defendants various information and permitted the examination of various evidence. On 10–30–61, the case came on for trial before the court and jury. On 10–30–61, counts 1 and 2 were dismissed. On 11–2–61, the jury returned a verdict of guilty on counts 3, 4, and 5. On 11–8–61, it was proved that the defendants had been convicted, on 10–7–58, of violation of the Federal Food, Drug, and Cosmetic Act, which conviction had become final before the violations alleged in this case (See D.D.N.J. No. 5762).

On 11–20–61, the defendants filed a motion for a new trial or, in the alternative, a motion in arrest of judgment. On 1–4–62, the court denied the defendants motions. On 2–14–62, Paxton was fined $5,000 ($2,500 each on counts 3 and 4), plus costs, and was sentenced to 6 years' imprisonment (3 years each on counts 3 and 4) and probation for 3 years (count 5) after service of the imprisonment; the corporation was fined $2,500 ($500 each on counts 3 and 5 and $1,500 on count 4).

*See also Nos. 7942, 7943, 7948–7953.

Thereafter, the defendants appealed the decision of the court. On 1–15–63, the United States Court of Appeals for the Seventh Circuit rendered the following opinion (313 F. 2d 152):

SWYGERT, *Circuit Judge:* "Defendants, Millpax, Inc., and Roy F. Paxton, were found guilty after trial by jury on three counts of a five-count indictment charging them with the misbranding of a drug known as 'Millrue,' in that its labeling failed to bear adequate directions for use, as required by Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 352(f)(1), and with causing the introduction or delivery for introduction into interstate commerce of such preparation, so labeled, in violation of Section 301(a) of the Act, 21 U.S.C. § 331(a), which prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded.

"Defendant Millpax, Inc., until March 23, 1961, was a corporation organized and existing under the laws of the State of Illinois, with office and principal place of business at Carlock, Illinois. Defendant Roy F. Paxton was secretary-treasurer and principal stockholder of the corporation.

"The product in question was packaged in bottles, bearing labels displaying the following printed and graphic matter:

Millrue
Iron Tonic
Hematinic
Stomachic
Contents 8 Fl. Oz.
Manufactured by
Millpax, Inc.
Carlock, Illinois

"The errors relied on for reversal arise out of the claimed inadequacy of the evidence to support the verdict, the charge to the jury (which was not objected to), and the failure of the trial court to acquit the defendants on the ground that, as a matter of law, they were entrapped.

"On May 2, 1960, Charles Armstrong, a Federal Food and Drug Inspector, wrote defendant Paxton from Memphis, Tennessee, ordering two bottles of Millrue. He enclosed a ten dollar money order. He stated in his letter that he had just been informed that he had cancer, and that he had read in the 'Herald of Health' magazine about 'your cancer cure—Millrue.' In response to his letter, he received a form letter,[1] prepared and signed by defendants' attorney, directing him to reread the article and to note that no claim is made by the writer or the manufacturer that Millrue cures anything. Concerning the claims made in the magazine article, the form letter to Inspector Armstrong said 'Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusions therefrom.' It is evident that the form letter was framed with the intention of drawing

[1] The alleged disclaimer letter reads as follows:

"Many thanks for your letter and order and it is regretted that Mr. Paxton cannot write to you personally as the mail has been tremendous and the Company is a small one.

"Your interest in the article referred to is natural, but terming the product a "blood purifier" therein is a misnomer. To "purify" connotes that as to any particular substance it is freed from extraneous matter or from anything that debases, pollutes, or contaminates it. The blood may be variable through bodily functions or malfunctions, and by ingestion, deficiencies when existent may be aided.

"If you will again read the article referred to which was written by Don C. Matcham, you will find that no claim is made that the product cures anything, either by the writer or the manufacturer. Any person may state what he believes the product has done or had not done for him, and any person is free to draw his own conclusion therefrom.

"If you still desire to order please advise by return mail, otherwise your money will be returned to you, as there is no desire by the manufacturer to sell this product under false pretenses.

"Sincerely,
Millpax, Inc.,
By----------
Theodore W. Hinds"

a cloak of legality around defendants' transactions. While there is a disclaimer in the letter as to any claims made directly by defendants, the jury is not required to blind itself to reality and fail to recognize the obvious intent of such a letter to adopt the testimonials made by others. No other purpose could be implied in view of the fact that the order from Armstrong specificially mentioned that he was suffering from cancer and that he wanted the Millrue to forestall his having to submit to surgery. We think it reasonable to recognize the plight of those suffering from cancer, their desperate frame of mind of which 'cancer remedy' salesmen are undoubtedly aware, and the influence these complementary attitudes have on a transaction such as the one in question. It is obvious that defendants intended to be understood as adopting as their own the magazine testimonials. The statement in the disclaimer letter that 'Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusions therefrom,' within the factual context present here, does not shield defendants from the consequences of their wilful acts.

"Armstrong, upon receipt of the form letter, wrote another letter requesting the Millrue. In response thereto he received a package in the United States Mails from Millpax, Inc., containing two bottles of Millrue.

"Both defendants were charged in Count III with responsibility for this interstate shipment of a misbranded drug.

"Defendants contend that the preparation known as Millrue is not a drug, but is a food for special dietary use excepted by the Federal Food, Drug, and Cosmetic Act, as amended, from inclusion in the term 'drug.' As discussed above, however, the intention of the defendants was to have prospective purchasers regard it as a drug and so use it; hence, their own actions classified Millrue as a drug. Thus, the use of the term 'drug' as used in the indictment and during the trial could not have been prejudicial to defendants.

"On April 16, 1960, Inspector Gebhart from the St. Louis office of the Food and Drug Administration and Mrs. Rachel Harrington, a clerical employee of that office, visited defendants' place of business at Carlock, Illinois. They posed as a married couple from Memphis, Tennessee and indicated they came to Carlock to see if defendant Paxton could find out what was wrong with Mrs. Harrington. They did not suggest to Paxton that she was suffering from any specific disease or ailment.

"Paxton asked her to s[i]t on a couch. As soon as she was seated, he began examining her left foot. When he examined the third toe, he told Mrs. Harrington that she had gas on the upper colon which is usually where cancer starts. In response to being asked if she had cancer, he stated that she did. Paxton recommended his Millrue tonic for this condition. He recommended also that she follow a diet and he gave her a printed copy of the directions for such diet. He told her that he had never lost a case of cancer or leukemia, and that she would be all right in three months. He also related that he had acquired the formula for Millrue about forty years ago from an old Indian doctor who wanted him to marry his daughter. The diet list and the label on the bottle were the only written directions given the agents for use of Millrue. Agent Gebhart and Mrs. Harrington purchased six bottles of Millrue and departed. Count IV of the indictment charged defendants with having caused to be delivered to Gebhart and Mrs. Harrington for introduction into interstate commerce the misbranded drug.

"A showing that drugs were introduced into interstate commerce is sufficient to show that they were, as well, delivered for introduction into interstate commerce. *United States* v. *Vrillium Products Co.*, 185 F. 2d 3 (7th Cir. 1950).

"The government contends that where a misbranded drug is sold and the seller has knowledge that the purchaser intends to transport the drug to another state this knowledge, in and of itself, is sufficient to bring the transaction within the ambit of 21 U.S.C. § 331(a), i.e., that the sale is an introduction or delivery for introduction into interstate commerce of the misbranded drug. It relies for support of this contention on *Drown* v. *United States*, 198 F. 2d 999 (9th Cir. 1952), cert. denied, 344 U.S. 920; and *United States* v. *Sanders*, 196 F. 2d 895 (10th Cir. 1952). For our purposes we need not decide if these cases support the broad interpretation given to 21 U.S.C. § 331(a) by the government.

"While it is true that defendant Paxton not only sold the misbranded product to the government agents and did so intending that it would be taken

by them to Tennessee, this intention was and could only have been formulated as a result of a representation made by the government agents which the evidence shows had no basis in reality. If we are to assume that the seller participates in some degree in the intent of the buyer so as to make the buyer's intent his intent, then we must also assume that, where a material misrepresentation by the buyer is made that the transaction is of an interstate character, a federal crime based on interstate commerce cannot exist. If this were not so, government agents would be able to turn a purely 'over-the-counter' sale of a misbranded product into a federal crime merely by an off-hand statement, completely untrue, that they intended to transport the goods across a state line. Here there was no evidence that Gebhart or Harrington came from Tennessee, intended to return to Tennessee, or had ever been in Tennessee. In fact, the evidence is conclusive that St. Louis, Missouri was their point of origin and also their destination when they left Carlock after making the purchase.

"The fact that they did cross a state line is immaterial in a situation where the crime is made federal only by virtue of the wrongdoers' participation in their expressed intent. The only intent ever expressed was totally false and we decline to extend defendants' knowledge of the agents' intent to that deliberately concealed so as to make them aware of the interstate nature of the sale. If this seems a formalism, it is a formalism required under our federal system—particularly where the statute specifically calls for an introduction or delivery for introduction into interstate commerce as a requirement and essential element of the corpus delicti. Situations not involving interstate commerce are not before us and we specifically decline to treat them. *Cf. United Cigar Whelan Stores Corp* v. *United States*, 113 F. 2d 240 (9th Cir. 1940); *Sherman* v. *United States*, 10 F. 2d 17 (6th Cir. 1926); *United States* v. *Abda*, 32 F. Supp. 23 (D.C. M.D. Pa. 1940). We are concerned solely with a statute that defines a criminal act under the cognizance of federal authority having as an essential element thereof, knowledge of or intent to engage in or affect interstate commerce and actions commensurate with such knowledge or intent.

"We think that the interstate element of the crime must rest on something more solid than the pretenses of government agents to satisfy the minimum requirements of basic fair play—that is, due process. Since the interstate element of Count IV was not proved, we hold that the conviction under that count must be vacated.

"On May 6, 1960, Jack A. Forbragd, an Inspector stationed in San Francisco, addressed a letter to defendant Paxton requesting a bottle of Millrue. The letter stated that he had stomach pains, was constipated, and was sure he had cancer. It further stated that he had read in the 'Herald of Health' magazine that Millrue was a cancer cure. He enclosed a money order for $5.20. In response, he received a bottle of Millrue. The labeling contained no reference to cancer, stomach pains or constipation. Defendants, at the trial, attempted to show that a disclaimer letter, worded identically to that sent to Inspector Armstrong, was mailed to Inspector Forbragd. Moreover, Paxton testified that Forbragd in a telephone call from San Francisco acknowledged receipt of the form letter and nonetheless ordered the drug. Forbragd denied receipt of any such letter or that he had made the telephone call. On cross-examination of defendants' witnesses, it was brought out that no attempt had been made to find a record of the telephone call; that the person who allegedly mailed the letter didn't remember mailing it; and that the carbon introduced and claimed to be a copy of the form mailed to Forbragd may have been prepared solely for the purposes of trial. The Forbragd sale was the basis for Count V of the indictment charging defendants with having caused to be introduced and delivered for introduction into interstate commerce a drug misbranded in that its labeling failed to bear adequate directions for use for the purposes and conditions for which the drug was intended, namely, the treatment of stomach pains, constipation, and cancer.

"It is elementary that where the ground for reversal is insufficiency of the evidence to support the verdict, the evidence must be construed in the light most favorable to the government and in the light of all reasonable inferences which the jury may draw therefrom. *Glasser* v. *United States*, 315 U.S. 60 (1942). Although defendants introduced versions of the transactions in ques-

tion different from those of the government, we are convinced that the jury was justified in accepting the government's proof. There is substantial evidence to support the verdict as to Counts III and V.

"Defendants, on appeal, raise for the first time the defense of entrapment as a matter of law. It is uniform practice for appellate courts to refuse to consider alleged errors not raised in the trial court unless the result would lead to a miscarriage of justice. *Ramirez* v. *United States*, 294 F. 2d 277 (9th Cir. 1961); *United States* v. *Sferas*, 210 F. 2d 69 (7th Cir. 1954), cert. denied, 347 U.S. 935. We are convinced that no injustice resulted from the failure of the trial court to rule that entrapment had been established as a matter of law. Entrapment as a matter of law is established only where undisputed testimony makes it patently clear that an otherwise innocent person was induced to commit the act complained of by the trickery, persuasion, or fraud of a government agent. *Sorrells* v. *United States*. 287 U.S. 435 (1932). We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that government agents used a ruse to conceal their identity does not require a different conclusion. The issue of entrapment was properly left to the jury.

"We have examined the instructions given by the trial judge and find them to have correctly stated the issues and the law governing the case. The instructions were not objected to at the trial and in the absence of substantial error capable of resulting in a miscarriage of justice, we decline to consider the assignment of error now raised for the first time on appeal. *United States* v. *Vasen*, 222 F. 2d 3 (7th Cir. 1955).

"The judgment entered by the District Court convicting defendants on Count IV is reversed. The judgment convicting defendants on Counts III and V is AFFIRMED."

On 1–26–63, the defendants filed a petition for a rehearing. On 2–21–63, the appellate court denied the petition for rehearing.

On 3–8–63, the defendants petitioned the Supreme Court of the United States for a writ of certiorari and, on 4–29–63, the Supreme Court denied the petition (373 U.S. 903). On 5–20–63, the defendants petitioned the Supreme Court for rehearing of its order denying the defendants' petition for writ of certiorari and, on 6–3–63, the Supreme Court denied the petition for rehearing (373 U.S. 954).

On 6–24–63, the District Court for the Southern District of Illinois denied the defendants' motion for the suspension of the 3-year imprisonment sentence imposed on Roy F. Paxton and the granting of probation; and the court directed Paxton to surrender himself to the United States marshal on 6–25–63.

7956. APC tablets. (F.D.C. No. 48573. S. Nos. 18–431 T, 18–618 T, 20–841 T, 20–844 T.)

INFORMATION FILED: 3–9–64, N. Dist. Tex., against Bloom's Edgewood Pharmacy, a corporation, Dallas, Tex., and Stanley H. Bloom, president.

ALLEGED VIOLATION: Between 9–12–61 and 9–19–61, after various quantities of aspirin, phenacetin, and caffeine, in powder form, had been shipped in interstate commerce into the State of Texas and had been fabricated into tablets known as *APC tablets*, at Dallas, Tex., a number of such tablets in unlabeled boxes were caused to be dispensed twice by the defendants in place of penicillin tablets requested for the self-treatment of venereal disease; and the act of causing the *APC tablets* to be dispensed as above resulted in the tablets being adulterated (count 2) and misbranded (count 1).

Between 1–30–62 and 1–31–62, while a number of *APC tablets* were being held for sale after shipment in interstate commerce, the defendants caused the article to be dispensed twice in unlabeled boxes in place of penicillin tablets re-

quested for self-treatment of venereal disease, which act resulted in the article being adulterated (count 4) and misbranded (count 3).

CHARGE: 501(d)(2)—while held for sale, *APC tablets* were substituted for another drug, namely, penicillin; 502(b)—the article failed to bear a label containing (1) name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of numerical count; 502(e)(2)—the labeling of the article failed to bear the common or usual name of each active ingredient including the name and quantity or proportion of acetophenetidin; 502(f)—the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warning against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration; and 502(i)(3)—the article was offered for sale under the name of another drug.

PLEA: Guilty.

DISPOSITION: 3–10–64. Corporation—not sentenced; individual—$1,000 fine; 1 years' imprisonment suspended and probation for 1 year.

7957. Amphetamine-containing capsules. (F.D.C. No. 49623. S. No. 24–750 A.)

QUANTITY: 1 btl. containing approximately 150 capsules at Calumet City, Ill., in possession of Dr. C. R. Goldstein, chiropodist.

SHIPPED: On and prior to 11–22–63, from outside the State of Illinois.

LIBELED: 11–26–63, N. Dist. Ill.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement since it was a prescription drug which was not in the possession of a person who was regularly and lawfully engaged in the manufacture, transportation, storage, or distribution, of prescription drugs and since the article was not to be dispensed as required by 503(b).

DISPOSITION: 2–26–64. Default—destruction.

7958. Procaine penicillin G and buffered penicillin G crystalline. (F.D.C. No. 49245. S. Nos. 48–285 X, 48–643/4 X.)

QUANTITY: 1,818 vials and 45 vials at Berkeley, Calif.

SHIPPED: Prior to 7–3–63, from outside the State of California.

RESULTS OF INVESTIGATION: The vials were found in a vacant house by an individual who turned them over to the police department.

LIBELED: 9–3–63, N. Dist. Calif.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs, and were in the possession of a person not regularly or lawfully engaged in the manufacture, transportation, storage, wholesale distribution, or dispensing of prescription drugs.

DISPOSITION: 1–8–64. Default—destruction.

7959. Ergot. (F.D.C. No. 49554. S. Nos. 32–486/7 X.)

QUANTITY: 1 drum containing 100 lbs., and 1 2-oz. pkg., at Palos Verdes Peninsula, Calif., in possession of Cornell Associates.

SHIPPED: In October 1963, from Jersey City, N.J., by S.B. Penick & Co.; and 10–8–63, from New York, N.Y., by Meer Corp.

LABEL IN PART: (Drum) "Whole Ergot NF * * * S.B. Penick & Co., * * * Jersey City, N.J. Caution: For Manufacturing Processing or Repacking" and (pkg.) "Meer Corporation * * * New York 36, N.Y. Ergot of Rye * * * Caution: For Manufacturing Processing or Repackaging."

LIBELED: 12–6–63, S. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs subject to the requirements of 503(b)(1), and the exemption for manufacturing use as provided by regulations had expired because shipment of the articles had been made to a person in whose possession the articles were not exempt from 502(f)(1).

DISPOSITION: 1–16–64. Default—destruction.

7960. Endozime Injectable. (F.D.C. No. 49923. S. No. 88–904 A.)

QUANTITY: 118 10-cc. vials at Norborne, Mo., in possession of Biolab Corp.

SHIPPED: 7–17–63, from Chicago, Ill.

LABEL IN PART: (Vial) "Multiple Dose Vial Endozime Injectable With B_{12} Each cc contains: Adrenal Cortex Injection U.S.P. XV 25 Mg. Methylandrostenediol 5 Mg. Vit. B–12 U.S.P. Crystalline 35 Mcg. Sodium Chloride 0.65%–Pectin 0.25% Methylcellulose U.S.P. 0.07% * * * Intramuscular Supplied by: Biolab Corporation Norborne, Missouri * * * Caution."

ACCOMPANYING LABELING: Leaflets entitled "Endozime Injectable (The modern Anabolic, Metabolic and Catabolic Formulation.) Description A formula incorporating biologically standardized adrenal cortex injection U.S.P. at 35 mg. per cc., methylandrostenediol at 5 mg. per cc., liver injection U.S.P. (from 20 mcgn activity/cc) 250 mg. per cc., with cyanocobalamin (vitamin B–12) at 30 mcgm per cc. The combination which thus provides 35 micrograms of Vitamin B–12 activity per cc."

RESULTS OF INVESTIGATION: The article was shipped in vials in clear plastic boxes to the dealer, who inserted the leaflets into the plastic boxes.

LIBELED: On or about 3–13–64, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the labeling of the article was false and misleading in that the ingredient statement "Each cc contains: Adrenal Cortex Injection U.S.P. XV 25 Mg." on the vial label was inconsistent with the statement "adrenal cortex injection U.S.P. at 35 mg." in the leaflet; 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from that requirement since the same information concerning the ingredients did not appear on the vial and in the leaflet; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirements since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 5–8–64. Default—destruction.

7961. Cormycin Spray. (F.D.C. No. 48830. S. Nos. 27–773/4 V.)

QUANTITY: 50 cases, each containing 12 20-cc. btls., and 33 cases, each containing 12 20-cc. btls., at Independence, Mo.

SHIPPED: 12–5–61, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Btl.) "Cormycin Spray A Buffered Aqueous Solution Each cc. containing: Phenylephrine HCl 0.1250%, Gramicidin, Crystalline 0.0055%, Neomycin Sulfate 0.1100%, Methapyrilene HCl, 0.2000%, Polymixin B Sulfate 2,400 Units * * * Dosage: * * * Note * * * Distributed by Cooperative Pharmacal Co. * * * Independence, Mo.," and the 33-case lot additionally labeled "Hydrocortisone Alcohol 0.0250%, Caution: Federal law prohibits dispensing without prescription."

LIBELED: 3–29–63, W. Dist. Mo.

CHARGE: 50-case lot, 502(a)—when shipped, the labeling of the article was misleading in that the appearance of the bottle and its contents, the name of the article, "*Cormycin Spray*," and the appearance of other printed and graphic matter on the bottle label in combination, created the impression that the article was the prescription drug which contained hydrocortisone and was marketed by the same firm under the same name; and 502(f)—the labeling failed to bear (1) adequate directions for use, and (2) a warning statement to avoid overdosage and follow directions for use carefully.

33-case lot, 502(a)—when shipped, the labeling of the article was misleanding in that the appearance of the bottle and its contents, the name of the article, "*Cormycin Spray*," and the appearance of other printed and graphic matter on the bottle label in combination, created the impression that the article was the nonprescription drug which does not contain hydrocortisone, and which was marketed by the same firm under the same name; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirements since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 4–30–64. Consent—claimed by Philadelphia Laboratories, Inc., for relabeling.

7962. Antacid No. 2 tablets. (F.D.C. No. 49244. S. No. 41–050 X.)

QUANTITY: 80 1,000-tablet btls., 3 25,000-tablet btls., and 62 1,000-tablet btls., at Newark, N.J., in possession of Old Empire, Inc.

SHIPPED: Between 3–30–62 and 4–13–62, from Brooklyn, N.Y.

LABEL IN PART: "Aromatic Antacid No. 2 Tablets Each Tablet Contains: Calcium Carbonate 0.23 Gm. (3½ gr.) Magnesium Carbonate 0.15 Gm. (2½ gr.) Bismuth Subnitrate 30 mg. (½ gr.) Aromatics Garde Drug Company Newark 4, New Jersey [or "Physician's Drug and Supply Co., Newark 4, New Jersey"]."

RESULTS OF INVESTIGATION: The article was shipped in bulk lots and repacked and labeled by the dealer.

LIBELED: 8–30–63, Dist. N.J.

CHARGE: 502(a)—while held for sale, the label (repack) contained false and misleading representations that the article was adequate and effective as a treatment for peptic ulcer; and 502(f)(1)—the labeling failed to bear adequate directions for use for the treatment of peptic ulcer, a condition not amenable to self-treatment.

DISPOSITION: 10–23–63. Consent—claimed by Physician's Drug & Supply Co., Newark, N.J., and relabeled.

7963. Lanvite multiple vitamin and mineral tablets. (F.D.C. No. 49902. S. No. 18–928 A.)

QUANTITY: 603 100-tablet btls. and 9 1,000-tablet btls. at Buffalo, N.Y.

SHIPPED: 12–27–63, from Philadelphia, Pa., by Vitamix Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Lanvite Multiple Vitamins and Minerals. Dosage: Adults 1–3 Tablets Daily. Each tablet contains: Hematinics * * * Folic Acid (Vitamin) .1 mg. * * * Lipotropic Factors Methionine (Amino Acid) 25 mg. Vitamins * * * Minerals Calcium (from Dicalcium) 23 mg. Phosphorous (Phosphate 100 mg.) 18 mg. * * * Sodium Molybdate 3 mg. * * * Distributed by The Buffalo Pharmaceutical Supply Corp. Buffalo, N.Y."

LIBELED: 3–24–64, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article, "Hematinics" and "stimulant for the hematopoietic system in microcytic and nutritional anemia," was false and misleading since the article was not adequate and effective for the treatment of anemia; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use of the article as a lipotropic factor or agent which it was represented to be.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–7–64. Consent—claimed by Buffalo Pharmaceutical Supply Corp. for relabeling.

7964. Rexair vacuum cleaner. (F.D.C. No. 50131. S. No. 43–838 A.)

QUANTITY: 13 devices at Grand Junction, Colo., in possession of Rexair Sales & Service Co.

SHIPPED: Between 3–11–64 and 4–17–64, from Amarillo, Tex., by Rexair Sales & Service.

LABEL IN PART: "Made by Rexair, Inc. Syracuse, New York * * * Rainbow Model D."

ACCOMPANYING LABELING: Sales manuals entitled "The Exclusive Story * * * 165,000 of the Country's Leading Doctors"; journals entitled "Journal of Allergy," Sept.–October 1961 issue; magazines entitled "Hospital Magazine," November 1961 issue; and pamphlets entitled "The New Rainbow Washes The Air Through Water."

RESULTS OF INVESTIGATION: The article was a household vacuum cleaner consisting of a cleaning tube and hose attached to a ¾-horsepower electric motor and an internal clear plastic basin and metal tank-type container. Seven metal or plastic accessories for specialized household cleaning tasks were available. In use, the device was plugged into the house current and dust and dirt were sucked through the cleaning tube into a water-bath which was supposed to remove impurities and to humidify the air.

LIBELED: 5–15–64, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment of bronchial attacks and respiratory ailments, and that use of the article was beneficial to allergy sufferers; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use of the article to forestall asthma and sinus attacks by eliminating dust from the air, to clean the air of germs and bacteria, to lessen susceptibility

to colds and for asthmatic and sinus conditions, which were the purposes and conditions for which the article was represented in oral statements by Mr. Norman Edwards, a salesman for the dealer.

DISPOSITION: The article was claimed by Dillon W. Kline and, with his consent, a decree of condemnation was entered on 8–20–64, which ordered the release of the article for relabeling and also ordered that the claimant and his employees and agents should at no time sell or promote the article in writing, advertising, or orally, for forestalling asthma and sinus attacks, for cleaning the air of germs and bacteria, to lessen susceptibility to colds, for the treatment of asthmatic and sinus conditions, bronchial attacks and respiratory ailments, or for similar medical purposes.

7965. Leisure Lounge vibrating device. (F.D.C. No. 50127, S. No. 45–241 A.)

QUANTITY: 4 unlabeled devices, at Denver, Colo., in possession of Niagara of Colorado.

SHIPPED: On unknown dates, from Brocton, Silver Creek, or Buffalo, N.Y., by Niagara Therapy Manufacturing Corp.

ACCOMPANYING LABELING: Leaflets entitled "Niagara Cyclo Massage * * * Imagine" and "From Niagara"; booklets entitled "Instruction Manual"; business reply cards entitled "Science at Work"; banners reading in part "For the relief of aches and pains, nervous tension, sleeplessness, backaches, tired feet, muscle spasms, arthritis, rheumatism, and to increase circulation wherever applied"; posters entitled "Niagara Invites You," "Niagara Dual Thermo-Cyclopad," "Niagara 3 Way Action," and "Niagara Cyclo-Massage"; and business reply cards entitled "Arthritis?"

RESULTS OF INVESTIGATION: The article was an electrical device containing vibratory mechanisms and units for the production of heat, which was intended for home-application to the body.

LIBELED: 5–12–64, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for arthritis, rheumatism, nervous tension, sleeplessness, backaches, tired feet, muscle spasms, aches and pains, and to increase circulation; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for removing cortisone from the blood and for restoring a dog's hair by increasing circulation of the dog's blood, which were the conditions and purposes for which the article was recommended in oral statements made by a salesman of Niagara of Colorado.

DISPOSITION: 6–22–64. Default—the device was released to a public institution after the removal of all heating, massage and other mechanical units which were released to the Food and Drug Administration. All the accompanying labeling was destroyed.

7966. Whirlpool bath device. (F.D.C. No. 49907. S. No. 79–994 A.)

QUANTITY: 13 individually ctnd. devices at Brooklyn, N.Y., in possession of American Home Therapy, Inc.

SHIPPED: 1–7–64, from Bloomington, Ill.

LABEL IN PART: (Shipping ctn.) "To Amer Home Therapy Corp * * * Revitalizing . . . Refreshing * * * Whirlpool Bath."

ACCOMPANYING LABELING: Leaflets entitled "The Magic of Water Therapy in your home."

LIBELED: 3–17–64, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of nervous tension, arthritis, rheumatism, polio, toning muscles and body tissues, promoting refreshing sleep, and conditioning the body; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of blood clots and hemorrhoids, arthritis, rheumatism, a break in the bone, softening the muscles, restoring circulation of the blood, and for healing a lot better and quicker; which were the purposes for which the article was offered in oral statements made on 1–8–64, by Seymour Katz, a sales representative of the American Home Therapy Corp., during a sales demonstration.

DISPOSITION: 5–15–64. Default—delivered to the Food and Drug Administration.

7967. **Bath aeration device.** (F.D.C. No. 48803. Inj. No. 478. S. Nos. 60–130/3 V, 68–189 V.)

QUANTITY: 16 devices at East Point, Ga.

SHIPPED: Between 9–24–62 and 3–4–63, from Berkeley, Calif., and Hackensack, N.J.

ACCOMPANYING LABELING: Booklet entitled "For Professional Use Only Partial List of Professional Users"; folder entitled "The Whole Family Loves Jacuzzi Whirlpool Bath, Bulletin No. JWG–2"; newspaper advertisement proof from a local newspaper entitled "Everybody Loves A Warm Bath and a Professional Massage"; sheet on the letterhead of Charles Newell Mell, MD., entitled "For Professional Use Only"; leaflets entitled "Jacuzzi Whirlpool Bath Instructions and General Information," "Jacuzzi Whirlpool Bath, Bulletin No. JWB–1," "Jacuzzi Whirlpool Bath, Bulletin No. JW–M2," "Brine Bath Treatments For Decubitus Ulcers," "The Use of the Whirlpool Bath, by Herman J. Bearzy, M.D. For Professional Use Only," "Memorandum on Subject of the Safety of the Jacuzzi Whirlpool Bath by Candido Jacuzzi July, 1961"; and newspaper and magazine reprints entitled "Home Therapy Hailed in Arthritis Struggle," "A Physical Fitness Program For Home Use," and "Directional Hydrotherapy."

RESULTS OF INVESTIGATION: Investigation indicated the article to be a submersible, electric water pump with an attached tube for aerating the water before ejection from the pump.

LIBELED: 3–11–63, N. Dist. Ga.; libel amended 4–15–63 and 9–20–63.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective in the treatment of traumatic sprains, strain, contusions, bursitis, bone injuries, circulatory disturbances, inflammation, edema, ulcers, pectoral sclerosis, peripheral nerve injury, neuritis, arthritis, and postpoliomyelitis; 502(f)(1)—the labeling of the article failed to bear adequate direction for use for traumatic sprains, strain, contusions, bursitis, bone injuries, circulatory disturbances, inflammation, edema, ulcers, pectoral sclerosis, peripheral nerve injury, neuritis, arthritis, and postpoliomyelitis, which were the conditions for which the article was offered in oral statements made 12–19–62 and 1–27–63, by Martin B. Fanarjian, salesman for Fanarden Equipment Co., during demonstrations in the homes of Food and Drug Administration inspectors, at Smyrna, Ga.

DISPOSITION: 9–20–63. Consent—claimed by Paul Hayden of East Point, Ga., for relabeling. The consent decree also prohibited the claimant from holding

for sale or causing the holding for sale, or distributing or causing the distribution of the articles of device, Jacuzzi Whirlpool Baths, or any similar article of device, after its shipment in interstate commerce, which: (a) was accompanied by labeling consisting of the booklet entitled "For Professional Use Only Partial List of Professional Users," leaflet entitled "Brine Bath Treatment for Decubitus Ulcers," leaflet entitled "The Use of the Whirlpool Bath, by Herman J. Bearzy, M.D. For Professional Use Only," sheet on letterhead of Charles Newell Mell, M.D., entitled "For Professional Use Only," and any other labeling designated as or intended to be used as "professional literature"; (b) was accompanied by any labeling which represented and suggested that the article was adequate and effective in the treatment of traumatic sprains, strain, contusions, bursitis, bone injuries, circulatory disturbances, inflammation, edema, ulcers, pectoral sclerosis, peripheral nerve injury, neuritis, arthritis, and postpoliomyelitis; and (c) was sold and offered for sale without labeling bearing adequate directions for use for the diseases, conditions, and purposes for which it was intended, and for which it was represented by any means, to the public.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7968. Dapco-S tablets, Double Hyatal tablets, Douchett powder, Vee-6 tablets, Du-Mate tablets. (Inj. No. 260. S. Nos. 43–878 M, 83–895/6 M, 87–322 M, 87–381 M, 87–415 M.)

PETITION FILED: 9–19–58, S. Dist. Ill., against Schlicksup Drug Co., a corporation, Peoria, Ill., to show cause why the firm should not be punished for criminal contempt with respect to shipments of adulterated and misbranded drugs in violation of the temporary injunction which had been entered against the firm on 10–21–53 (see D.D.N.J. No. 4593).[1]

SHIPPED: Between 2–8–57 and 11–14–57, from Peoria, Ill., to St. Louis and Overland, Mo., and Davenport, Iowa.

LABELS IN PART: (Btls.) "Dapco-S Each tablet contains: Dextro-amphetamine sulfate 5 mg.," "Double Hyatal Repeat Action Each tablet supplies 2 complete doses. Directions:," "Douchett Powder Violet Each ounce contains: Ammonium Alum, Dried 101 gm.," "Vee-6 Vitamin Spheroids Each Contains Niacinamide 20.0 mg.," and "Du-Mate Repeat Action Each tablet supplies 2 complete doses Usual Dose: 1 tablet."

CHARGE: 501(c)—when shipped, the strength of the articles differed from that which they were represented to possess; and 502(a)—the labeling of the articles contained false and misleading statements with respect to the quantity of ingredients contained in the articles.

PLEA: Not guilty.

DISPOSITION: On or about 10–26–61, an order to show cause was entered. On 1–15–62, the defendant filed a motion that the allegations with respect to the

*See also Nos. 7941, 7944, 7953, 7956, 7969.

[1] On 10–26–61, after consideration of the briefs and arguments of counsel, the court denied the Government's motion to make the temporary injunction permanent, and in accordance with defendants' motion ordered that the temporary injunction be dismissed without prejudices to the pending contempt action.

shipments made prior to 11–14–57, be stricken on the grounds that they occurred more than one year prior to the filing of the petition and were barred by reason of the limitation provision set forth in 18 U.S.C.A. 402 and 3285. The court denied such motion. On 1–15–62, the case came on for trial before the court and testimony of the parties was concluded on 1–17–62.

On 7–30–62, the following judgment was entered (206 F. Supp. 801) :

MERCER, *District Judge:* "This cause coming on to be heard on the government's petition for order to show cause why the Schlicksup Drug Company, Inc., the defendant herein, should not be punished for criminal contempt, and the Court having heard the evidence submitted thereon by the parties hereto, and having examined the written arguments and briefs of counsel, and being now fully advised in the premises, finds as follows :

"1. Defendant, Schlicksup Drug Company, Inc., a corporation under the laws of the State of Illinois, and is and has been continuously since 1951 engaged at Peoria, Illinois, in the District and Division aforesaid, in the business of manufacturing, preparing, packing, distributing, and selling drug products.

"2. Defendant has been continuously since 1951 and is now introducing and delivering for introduction and causing to be introduced and delivered for introduction into interstate commerce at Peoria, Illinois, certain of said drug products.

"3. On October 21, 1953, this Court entered an order for temporary injunction enjoining defendant from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered, for introduction into interstate commerce, at and from Peoria, Illinois, in violation of Section 331(a) of Title 21 U.S.C., articles of drugs adulterated within the meaning of Section 351(c) of said Title, because their strength differs from that which they are represented to possess and/or misbranded within the meaning of Section 352(a) of said Title because of false and misleading statements in the labeling of said drug with respect to the quantity of ingredients contained in said article.

"4. Said temporary injunction was based on the Court's findings that :

(a) Much of the equipment used by the defendant in the manufacture and preparation of drug products was inadequate, unsuitable, in a poor state of repair, and inaccurate ;

(b) There was laxity in the control of the identification, analysis, and formulas in the preparation of the firm's drug products ;

(c) The deficiencies found in several finished products which were shipped in interstate commerce resulted from the inadequate manufacturing methods.

"5. Said temporary injunction remained in full force and effect throughout the years 1956 and 1957.

"6. The president and responsible managerial personnel of the Schlicksup Drug Company, Inc., had complete knowledge of the terms of said injunction from the time of its issuance.

"7. Each of the products described in government's petition for order to show cause, to wit, Dapco-S, Double Hyatal, Douchett Powder, Vee-6 and Du-Mate are articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in man, or intended to affect the structure or function of the body of man.

"8. The above-described products were introduced into interstate commerce by the defendant company between February and November of 1957.

"9. The product, 'Dapco-S,' described in paragraph 3(a) of the government's petition, was 35 percent deficient in the amount of dextro-amphetamine sulfate declared on its label when introduced into interstate commerce by defendant.

"10. The label on the product, 'Double Hyatal,' as described in paragraph 3(b) of government's petition, states that each tablet supplies two complete doses. However, when introduced into interstate commerce by defendant, this product would release only one dose while in the human digestive system. The failure of one dose to be released is equivalent to a deficiency of 50 percent of the active ingredients, which the product's label states are contained in each tablet.

"11. The product, 'Douchett Powder,' described in paragraph 3(c) of government's petition, when introduced by defendant into interstate commerce, contained 49 percent less than the amount of dried alum which the product's label stated was contained therein.

"12. The product, 'Vee-6' described in paragraph 3(d) of government's petition, when introduced into interstate commerce by defendant, was more than 20 percent deficient in the amount of Niacinamide which its label stated it contained.

"13. The label of the product, 'Du-Mate,' described in paragraph 3(e) of government's petition, states that each tablet supplies two complete doses. However, when introduced into interstate commerce by defendant, this product would release only one dose while in the human digestive system. The failure of one dose to be released is equivalent to a deficiency of 50 percent of the active ingredients, which the product's label states are contained in each tablet.

"14. The product, 'Vee-6,' described in paragraph 3(f) of the government's petition, when introduced into interstate commerce by the defendant, was more than 20 percent deficient in the amount of Niacinamide which its label stated it contained.

"15. The basic criteria employed in establishing control methods by the Schlicksup Company and the consulting firm of Scientific Associates was economic. The specific changes effected were influenced entirely by the cost to the company rather than the desire to make certain that the actual strength and quantity of the drug ingredients was as the label declared them to be.

"AND THE COURT adopts the following as its

CONCLUSIONS OF LAW

"1. The articles prepared, package[d], and manufactured by the defendant, as described in paragraphs 3(a) through 3(f) of the government's petition, are articles of drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)].

"2. Defendant's lax and inadequate manufacturing practices have resulted in the production of drugs which are misbranded and adulterated under the terms of the Federal Food, Drug, and Cosmetic Act.

"3. That the articles of drug described in paragraph 3(a) through 3(f) of the government's petition, when introduced into interstate commerce by defendant, were adulterated and misbranded within the meaning of Section 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351(c) and 352(a)].

"4. Defendant's failure to eliminate the inadequacies in its manufacturing processes, was deliberate and not inadvertent and said violations are found to have been done wilfully and intentionally.

"5. Said introduction into interstate commerce of adulterated and misbranded drug products is a violation of Section 331(a) of Title 21 U.S.C. and also a violation of the order for temporary injunction issued by this Court on October 21, 1953.

"6. Although I am satisfied that the government need not prove willful intent, I find that the defendant corporation had such intent and, accordingly, is adjudged guilty of criminal contempt of the order for temporary injunction.

"I have found that the defendant wilfully, knowingly and intentionally violated the injunction. Defendant has earnestly advanced the argument that there is a necessity that the government prove intent and because of the earnestness of defendant in this regard, I feel constrained to discuss this argument.

"In a proceeding for criminal contempt, alleging disobedience of a temporary injunction restraining defendant from delivering into interstate commerce in violation of 21 U.S.C.A. 331(a), articles of drugs adulterated within the meaning of 21 U.S.C.A. 351(c) or misbranded within the meaning of 21 U.S.C.A. 352(a), does the government have the burden of proving specific intent to violate the Act and the injunction?

"The only pronouncement by any court upon this precise question is a dictum in *United States* v. *Wilson-Williams, Inc.*, No. 149–6, S.D.N.Y. (1961). There the court said that specific intent is not an element of the government's proof upon a charge of criminal contempt for the violation of an injunction restraining the interstate shipment of misbranded drugs, for the reason that the proof required to sustain a contempt charge should not be greater than that required to sustain a criminal conviction under the Food, Drug, and Cosmetic Act. It would be, the court said, an anomaly to require proof of specific

intent in the contempt situation when no such requirement was necessary to prove a criminal violation.

"After a review of the precedents, I am convinced that the result suggested by *Wilson-Williams* is correct for the reasons hereinafter set forth. I do not necessarily agree that the anomaly suggested in that opinion is apt, but I think it must be recognized that, in the matter of the elements of proof required, where the violation of an injunction order may also constitute a substantive crime forbidden by a statute, the contempt partakes of an analogous relationship to the substantive crime.

"Certainly, it is not necessary, as defendant seem[s] to suggest, to ignore the statute in the contempt situation. Mr. Justice Frankfurter, speaking for the Court, in *United States* v. *Dotterweich*, 320 U.S. 277, said of the Food, Drug, and Cosmetic Act at pages 280–281:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirements for criminal conduct—awareness of some wrongdoing. In the interest of a larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relationship to a public danger. *United States* v. *Balint*, 258 U.S. 250. And so it is clear that shipments (of drugs) are "punished by the statute if the article is misbranded (or adulterated), and that the article may be misbranded (or adulterated), without any conscious fraud at all. * * *." Citing *United States* v. *Johnson*, 221 U.S. 488, 497, 498.

At pages 284–85 Mr. Justice Frankfurter said:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

"The Act is remedial, *c.f.*, *United States* v. *Dotterweich*, *supra*, and its provisions may be enforced with either an injunction proceeding under 21 U.S.C.A. 332, or by a criminal proceeding under 21 U.S.C.A. 333. In cases of flagrant violation, the Act expressly provides that the government, by alleging specific intent 'to defraud or mislead,' may charge a felony punishable by up to three years in prison, of a fine of not more than $10,000.00, 21 U.S.C.A. 333(b).

"A reading of the Act requires the recognition that a substantial interrelationship exists between the criminal remedial provisions of the Act and a contempt proceeding growing out of the violation of a remedial order based upon the Act. Adulteration and misbranding, as defined by the Act,[1] may be enjoined in the absence of proof of any specific intent in the violation found to exist. It would be anomalous, indeed, therefore, to require proof of specific intent in continued violations in violation of an injunction before the court which issued the injunction could enforce it by a contempt proceeding. Such a result would not only defeat the purposes of the Act, but it might also sterilize the court's power to compel obedience to its orders.

"Defendant argues that *United States* v. *Kroger Grocery & Baking Co.*, 7 Cir., 163 F. 2d 168, is controlling. Not so. Unquestionably, we are dealing with a criminal contempt here which is a punitive proceeding *Gompers* v. *Bucks Stove*

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[1] A drug or device shall be deemed to be adulterated—

* * * *

"(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compedium, * * *.

"(c) If it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." 21 U.S.C.A. § 351.

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular." 21 U.S.C.A. § 352.

& R. Co., 221 U.S. 418, 31 S. Ct. 492, 498–99; *Reich* v. *United States*, 1 Cir., 239 F. 2d 134, and a proceeding in which the defendant is accorded the fundamental safeguards of criminal procedure. *Gompers* v. *Bucks Stove & R. Co.*, *supra*. It does not follow from that fact that intent is an essential element of the government's proof in every case. The opinion of the court in *Kroger* points out that intent may be imputed from the doing of an act prohibited by statute, although the act done does not involve turpitude. 163 F. 2d at 173. So too with criminal contempt. In *United States* v. *Ford*, D. Mont. 9 F. 2d 990, 992, the court said:

> In contempt, as in many varieties of crime, not always need there be an evil quality of mind. It suffices it the latter's equivalent appears in forgetfulness, neglect or failure or of indifference to duty or consequences.

"The *Kroger* case was a contempt proceeding for violation of an injunction issued pursuant to the provisions of the Emergency Price Control Act, 50 U.S.C.A. App. 901 et seq. Specific intent was an essential element of criminal sanctions imposed by that statute. Kroger admitted the overceiling price sales charged by the government, but specifically denied any intent to violate the ceiling price provisions of the Act. The request for a contempt order charged knowing, flagrant and wilful disobedience of the order, and the sole issue presented at a lengthy trial was the element of the intent with which the sales had been made. In view of that charge, and in view of the provisions of the OPA Act, the court held that specific intent must have been proved. At page 174, in discussing the import of the criminal provisions of the Act, the court's language implies that the contempt proceeding partook of the character of the substantive crimes created by the statute.

"Finally, I reject defendant's argument that the government charged specific intent in its contempt petition, and that it must, therefore, bear the burden of proving that element. Reference is made by defendant to the following language from the petition:

> Thereafter, with full knowledge of said temporary injunction and in defiance of its terms * * *, the defendant herein *did disobey and violate* said injunction * * *. (Emphasis by counsel.)

"It requires a distortion of meaning of the emphasized phrase, even if we throw in 'defiance' as well, to read into that paragraph an allegation of specific intent.

"Assuming, *arguendo*, however, that intent is thereby alleged, the allegation is surplusage, and not essential to a statement of the charge of contempt.

"The function of a criminal contempt is the protection of the courts in the exercise of their allotted powers. *Gompers* v. *Bucks Stove & R. Co.*, *supra*, 31 S. Ct. at 501. That function may not be thwarted by a surplusage of allegations in a petition calling a contempt to the court's attention. I do not read the *Kroger* case as requiring such a result. As the court there suggested, criminal contempt is not a constant and fixed substantive crime, inflexible in its requirements as to proof. On the contrary, specific intent may, or may not, be an essential element. C.f., 163 F. 2d at 173. Whether it is or not depends upon the scope of the court's order, the nature of the practice enjoined and the character of the act alleged to constitute a contempt.

"I hold that proof of intent and wilfullness is not an essential element of the contempt here charged.

"It is the Order of the Court that the defendant pay a fine to the United States of America in the sum of Two Hundred and Fifty Dollars and that it pay the costs of suit."

On 8–3–62, the defendant served a motion for judgment of acquittal or, in the alternative, a new trial, which motion recited various grounds, including the following: that the court's findings and conclusions determining the defendant to be guilty of wilful and knowing intent were not supported by any substantial evidence in the record; and that the court's conclusion of law, that wilful intent was not a necessary element for a finding of guilt of the defendant, was in error, in that in a criminal contempt proceeding the defendant must be

proven guilty beyond a reasonable doubt of criminal intent in committing the acts complained of.

On 2–21–63, the Government filed a motion to tax costs in the amount of $1,928.32 in addition to the fixed costs which amounted to $60. On 3–20–63, the court denied the defendants' motion and granted in part the Government's motion. The defendant was fined $250, plus $660 costs ($60 of fixed costs and $600 of additional costs).

7969. Ascorbic acid tablets. (F.D.C. No. 49689. S. Nos. 21–788/9 V, 22–628 V, 22–590 V.)

INFORMATION FILED: 4–1–64, S. Dist. Calif., against Rabin-Winters Corp., El Segundo, Calif.

SHIPPED: Between 2–16–62 and 3–1–62, from El Segundo, Calif., to Manitou Springs, Colorado Springs, and Denver, Colo., and Albuquerque, N. Mex.

LABEL IN PART: (Btl.) "Gray Cross Prescription Purity Vitamin C (Ascorbic Acid) 100 mg. 100 Tablets * * The Rabin Company El Segundo, Calif."

CHARGE: 501(b)—when shipped, the strength of the article differed from, and its quality or purity fell below, the standard for *ascorbic acid tablets* set forth in the United States Pharmacopeia since the article failed to comply with the identification tests of the standard and possessed a potency of less than 95 percent of the labeled amount of ascorbic acid; 501(d)(2)—a substance, namely, nicotinic acid tablets, had been substituted wholly or in part for *ascorbic acid tablets;* 502(a)—the label statement "Vitamin C (Ascorbic Acid) 100 mg. * * * For the treatment of Vitamin C deficiency" was false and misleading since each tablet of the article contained substantially less than 100 milligrams of ascorbic acid, and when the article was taken as directed it was not an adequate and effective treatment of vitamin C deficiency since it contained little or no ascorbic acid; and 502(i)(3)—the article was caused to be offered for sale and sold under the name of another drug, namely, *ascorbic acid tablets*, whereas the article was not *ascorbic acid tablets* but was nicotinic acid tablets.

PLEA: Nolo contendere.

DISPOSITION: 5–19–64. $800 fine.

7970. Menodol tablets. (F.D.C. No. 47127. S. No. 35–880 R.)

INFORMATION FILED: 5–17–63, E. Dist. N.Y., against Barrows Chemical Co., Inc., Inwood, Long Island, N.Y.

ALLEGED VIOLATION: On 9–29–60, the defendant gave to a firm engaged in introducing drugs into interstate commerce, an invoice containing a guaranty that the merchandise listed on the invoice had been produced in full compliance with all provisions of the Federal Food, Drug, and Cosmetic Act. On 9–29–60, the defendant rendered the guaranty false by causing to be shipped, on the order of the holder of the guaranty, for delivery in Puerto Rico, the quantity of *Menodol tablets* listed on the invoice, which tablets were adulterated and misbranded.

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess since each tablet contained less mephenesin, sodium salicylate, and sodium gentisate than it was represented to contain; and 502(a)—the label statement "Each tablet contains Mephenesin N.N.R.—250 mg., Sodium Salicylate—200 mg., Sodium Gentisate—100 mg." was false and misleading.

PLEA: Nolo contendere.

DISPOSITION: 5–14–64. $500 fine.

7971. Imitation Dexamyl Spansule capsules (2 seizure actions). (F.D.C. Nos. 49620, 49658. S. Nos. 3–848 X; 55–442 X.)

QUANTITY: 4 btls. containing a total of 943 capsules at Clarksburg, W. Va.; 5 btls. containing a total of 1,109 capsules, at Dayton, Ohio.

SHIPPED: 8–13–63 and 9–6–63, from New York, N.Y., and Chicago, Ill., by Biddle Purchasing Co.

RESULTS OF INVESTIGATION: Analysis showed that both lots contained amobarbital and dextro-amphetamine sulfate, and that they were not the product of Smith, Kline and French Laboratories.

LIBELED: 11–26–63, N. Dist. W. Va.; 12–26–63, S. Dist. Ohio.

CHARGE: 501(d)(2)—when shipped, a product consisting of *imitation Dexamyl Spansule capsules* had been substituted for Dexamyl Spansule capsules; 502(a)—the name of the article, "Dexamyl Spansule" capsules, was false and misleading as applied to a product which was an imitation of Dexamyl Spansule capsules; and 502(i)(2)—the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 12–17–63, 1–31–64. Default—destruction.

7972. Imitation Dexamyl Spansule capsules. (F.D.C. No. 49618. S. No. 17–946 X.)

QUANTITY: 5 250-capsule btls. at Louisville, Ky.

SHIPPED: 9–11–63, from Evanston, Ill., by J. & J. Medical Supply Co.

LIBELED: 11–27–63, W. Dist. Ky.

CHARGE: 501(d)(2)—when shipped, imitation "Dexamyl" had been substituted for "Dexamyl"; 502(a)—the name of the article, "Dexamyl," was false and misleading; 502(i)(2)—the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 2–14–64. Default—destruction.

7973. Buffered penicillin G sodium powder. (F.D.C. No. 48847. S. No. 65–839 V.)

QUANTITY: 2 ctns. containing 100 unlabeled 20-cc. vials each, 1 ctn. containing 21 unlabeled 20-cc. vials, 1 ctn. containing 86 unlabeled 20-cc. vials, 74 ctns. containing 200 unlabeled 20-cc. vials each, and 1 ctn. containing 74 labeled 20-cc. vials, at Parsippany, N.J., in possession of Pure Laboratories, Inc.

SHIPPED: Between 10–19–62 and 2–15–63, the unlabeled vials were shipped from New York, N.Y., by Jerdan Chemical Co., and the labeled vials (a return shipment), by American Quinine Co.

LABEL IN PART: (Labeled vials) "Buffered Penicillin G Sodium For Injection U.S.P. * * * Distributed by American Quinine Co. New York, N.Y."; (ctns. of unlabeled vials) "Penicillin G Sodium Buffered c̄ Sodium Citrate 5,000,000 Units * * * Unlabeled Philadelphia Laboratories, Inc. Philadelphia 23, Pa."

RESULTS OF INVESTIGATION: Examination showed that the article contained mold.

LIBELED: 4–15–63, Dist. N.J.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, Buffered Penicillin G For Injection, the name of which was

recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the standard set forth in such compendium.

DISPOSITION: 2–5–64. Consent—claimed by the manufacturer, Philadelphia Laboratories, Inc. The *buffered penicillin G sodium powder* was removed from the vials for remanufacturing and the vials were destroyed.

7974. Syringes. (F.D.C. No. 49204. S. No. 70–849 V.)

QUANTITY: 8½ cases, each containing 4 100-syringe ctns., at Indianapolis, Ind.

SHIPPED: 12–26–62, from Indianapolis, Ind., to Chicago, Ill., by General Medical Supply Co., and returned to Indianapolis on 1–10–63.

LABEL IN PART: (Ctn.) "Sterile 100–TB–27x½ Steri Syringe * * * General Med. * * * Lot 225"; (envelope) "Sterile Steri-Syringe * * * Only Use Once and Discard"; and (syringe) "Steri-Syringe * * * Tuberculin."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable micro-organisms.

LIBELED: 7–31–63, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the label statement (carton and envelope) "Sterile" was false and misleading as applied to an article which was not sterile in that it was contaminated with viable micro-organisms; and 501(c)—the quality of the article fell below that which it was purported to possess.

DISPOSITION: On 10–23–63, a consent decree of condemnation was entered and, on 5–1–64, an order was entered on joint motion of the claimant and the Government for destruction of the article.

7975. Rubber prophylactics. (F.D.C. No. 49521. S. Nos. 77–224 X, 77–388 X, 77–391 X.)

QUANTITY: 2 cases, each containing 40 ctns., each ctn. containing 3 boxes of 4 pkgs. of 12 *Safe Brand units* each; 9 cases, each containing 50 gross of *Chariot units;* and 8 cases, each containing 40 ctns., each ctn. containing 12 individually packaged *Texides units*, at New York, N.Y.

SHIPPED: 9–24–63 and 9–27–63, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: (Ctn., box, and pkg.) "Safe Brand Nipple End * * * Prophylactics * * * Pharma-Sales, Inc. Sole Distributors Rochester New York Sold Only By Pharmacists For The Prevention Of Disease"; (case) "Chariot Tubed GW From Killashun Sales * * * Akron 11, Ohio To Goodwear Rubber Co. * * * New York, New York" and (unit) "Chariot Sold For Prevention Of Disease Only"; (ctn. and pkg.) "Texide Prophylactics Sold For Prevention Of Disease Only * * * Assists In Protecting Health Through The Prevention of Venereal Disease And The Reinfection Of The Female With Trichomonas * * * Mfd. by L. E. Shunk Latex Prod. Div. of The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that 0.9 percent of the *Safe Brand units* tested, 0.8 percent of the *Chariot units* tested, and 0.9 percent of the *Texides units* tested, were defective in that they contained holes.

LIBELED: On or about 11–29–63, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements, (*Safe Brand*) "Sold Only By Pharmacists For The Prevention Of Disease," (*Chariots*) "Sold

For Prevention Of Disease Only," and (*Texides*) "Sold For Prevention Of Disease Only" and "Assists In Protecting Health Through The Prevention Of Venereal Disease And The Reinfection Of The Female With Trichomonas," were false and misleading.

DISPOSITION: 1–2–64. Default—destruction.

7976. Rubber prophylactics. (F.D.C. No. 50136. S. No. 13–479 A.)

QUANTITY: 80 ctns., each containing 12 12-unit pkgs., at East Hartford, Conn.

SHIPPED: 4–3–64, from Baltimore, Md., by Chief Sales, Inc.

LABEL IN PART: (Pkg.) "Sold For Prevention of Disease Only Cello's Prophylactics * * * Mfd. by The Killian Mfg. Div. of The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination of 117 units showed that 2 were defective in that they contained holes.

LIBELED: 5–22–64, Dist. Conn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements, "Sold For Prevention of Disease Only" and "Assists in Protecting Health Through the Prevention of Venereal Disease and of the reinfection of the female with trichomonas," were false and misleading as applied to a product containing holes.

DISPOSITION: 8–17–64. Default—destruction.

7977. Rubber prophylactics. (F.D.C. No. 49483. S. No. 2–475 X.)

QUANTITY: 400 ctns., each containing 72 2-unit pkgs., at Miami Beach, Fla.

SHIPPED: 9–16–63 and 9–18–63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Genuine Ramshead Prophylactics * * * Safeway Products Co., P.O. Box 4115 Miami Beach 41, Fla. * * * Sold For The Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 1.5 percent of the article examined contained holes.

LIBELED: 11–4–63, S. Dist. Fla.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading; and 502(b)(1)—the label failed to bear a qualifying phrase, such as "Manufactured for and Packed by . . .," "Distributed by . . .," or other similar phrase which expressed the facts, since Safeway Products Co. was not the manufacturer.

DISPOSITION: 1–30–64. Consent—claimed by M & M Rubber Co. and reconditioned.

7978. Rubber prophylactics. (F.D.C. No. 49441. S. Nos. 2–224/6 X.)

QUANTITY: 25 ctns., each containing 72 2-unit pkgs. labeled "Tops," 125 ctns., each containing 72 2-unit pkgs. labeled "Supreme," and 75 ctns., each containing 48 3-unit pkgs. labeled "Deluxe," at Columbus, Ga.

SHIPPED: 9–25–63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Tops Prophylactics M & M Rubber Co. Kansas City, Mo. * * * See Instructions Inside," "Supreme Prophylactics * * * C G Pritchett * * * Columbus, Ga. * * * Sold for the Prevention of Disease Only," and

"Deluxe Prophylactics * * * C G Pritchett * * * Columbus, Ga. Sold for the Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination, of 50 *Tops prophylactics* showed that 4 percent contained holes, of 50 *Supreme prophylactics* showed that 42 percent contained holes, and of 50 *Deluxe prophylactics* showed that 12 percent contained holes.

LIBELED: 11–1–63, N. Dist. Ga.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which is was purported to possess; 502(a)—the label statements "Sold for the Prevention of Disease Only" were false and misleading; and 502(b)(1)—C. G. Pritchett was not the manufacturer of the Supreme and Deluxe devices and their labels failed to bear a qualifying phrase such as "Manufactured for and packed by * * *", "Distributed by," or other similar phrase or phrases which explained the facts.

DISPOSITION: 1–29–64. Default—destruction.

DRUGS FOR VETERINARY USE*

7979. Farmade veterinary products. (F.D.C. No. 49713. S. Nos. 28–240 X, 60–086 X, 60–345 X, 55–075 A.)

QUANTITY: 411 12-unit boxes of 7½-gm. *Sulfon-O-Tabs*, 188 1¾-oz. btls. of *Pink-I-Mist*, and 117 6-unit boxes of 15-gm. *Sulfon-O-Tabs*, at Kansas City, Mo.

SHIPPED: Between 3–8–63 and 9–16–63, from Kansas City, Kans., by Curts Laboratories, Inc.

LABEL IN PART: (Box) "Farmade Sulfon-O-Tabs 7½ Grams [or "15 Grams"] For The oral treatment of certain bacterial diseases affecting farm animals * * * Sulfamerazine 1.25 Gms. Sulfamethazine 1.25 Gms. Sulfathiazole 5.0 Gms. Prepared for Kansas City Vaccine Co. Stock Yards Kansas City, Mo." and (btl.) "Farmade Pink-I-Mist Veterinary Sulfacetamide sodium 16⅔% Fluorescein For treating keratitis (pink-eye) and external infections susceptible to sulfonamide medication * * * Prepared for Kansas City Vaccine Co. Stock Yards Kansas City, Mo."

RESULTS OF INVESTIGATION: Analysis showed that the article, *Sulfon-O-Tabs*, contained essentially the declared amounts of total sulfonamides, but that undeclared sulfadiazine was present, and that, in one batch, sulfamerazine and sulfamethazine were below the declared amount.

Examination of the *Pink-I-Mist* showed that it contained mold.

LIBELED: 1–10–64, W. Dist. Mo.; libel amended 1–15–64.

CHARGE: *Sulfon-O-Tabs*, 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it was purported to possess; 501(d)(2)—sulfadiazine had been in part substituted for sulfamerazine and sulfamethazine; and 502(a)—the label statements "Sulfamerazine 1.25 Gms. Sulfamethazine 1.25 Gms." were false and misleading.

Pink-I-Mist, 501(c)—when shipped, the purity and quality of the article fell below that which it was purported to possess.

DISPOSITION: 4–22–64. Default—destruction.

7980. Dextro-50. F.D.C. No. 49558. S. No. 47–537 X.)

QUANTITY: 117 btls. at Springfield, Mo.

SHIPPED: 7–8–63, from East St. Louis, Ill., by Corn Belt Laboratories, Inc.

*See also No. 7947.

LABEL IN PART: "500 CC Dextro-50 Sterile Parental Solution Contains Dextrose U.S.P. 50 percent w/v Corn Belt Laboratories Inc. East St. Louis, Illinois Directions * * * available to Veterinarians only."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 40 percent sucrose and that no dextrose was present.

LIBELED: 12–9–63, W. Dist. Mo.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from and its quality fell below the standard set forth in such compendium; 501(d)(2)—sucrose had been substituted wholly or in part for dextrose; and 502(a)—the label statement "Contains Dextrose U.S.P. 50 percent" was false and misleading as applied to a product which contained no dextrose.

DISPOSITION: 1–14–64. Default—destruction.

7981. Medicated feed. (F.D.C. No. 50390. S. No. 59–158 A.)

QUANTITY: 66 50-lb. bags at Beatrice, Nebr., in possession of Chris', Inc.

SHIPPED: Active ingredients were shipped on 1–17–64, from Charles City, Iowa.

LABEL IN PART: (Bag) "Starter Pix Pioneer Poultry * * * Chris' Hatchery Beatrice, Nebraska"; (tag on bag) "Pioneer Starter Pix Medicated for coccidiosis prevention, growth stimulation, better pigmentation in chicks and growing chickens Active Drug Ingredients 3,5 Dinitrobenzamide 0.025% Acetyl-(para-nitrophenyl)-sulfanilamide 0.030% 3-Nitro-4 hydroxyphenylarsonic acid 0.005% * * * Directions * * * Mfg. by Pioneer Feed Co., * * * Beatrice, Nebraska."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 64 percent of the declared amount of 3,5-dinitrobenzamide, approximately 64 percent of the declared amount of acetyl-(para-nitrophenyl)-sulfanilamide, and approximately 62 percent of the declared amount of 3-Nitro-4-hydroxyphenylarsonic acid.

The article had been manufactured by the dealer, using active drug ingredients shipped as above.

LIBELED: 7–15–64, Dist. Nebr.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statements, "3,5 Dinitrobenzamide 0.025%," "Acetyl-(para-nitrophenyl)-sulfanilamide 0.030%," and "3-Nitro-4 hydroxyphenylarsonic acid 0.005%," were false and misleading as applied to a product containing less than the declared amounts of these ingredients; and 502(a)—the labeling contained statements which represented and suggested that the article was adequate and effective for coccidiosis prevention; which statements were false and misleading, since the article was not adequate and effective for such purpose because the active drug ingredients were deficient.

DISPOSITION: 9–25–64. Default—destruction.

7982. Medicated feed. (F.D.C. No. 50286. S. No. 55–994 A.)

QUANTITY: 22 100-lb. bags at Ainsworth, Nebr., in possession of Rogers Grain & Feed.

SHIPPED: 4–27–63, from Chicago, Ill., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Tag on bag) "Rogers 0.0022% Diethylstilbestrol Mix in 42% Beef Supplement Feed at the rate of one (1) pound per animal day * * * Active Drug Ingredient Diethylstilbestrol 0.0022% * * * Manufactured by Rogers Products Co. Ainsworth, Nebraska * * * for fattening steers and heifers in the feedlot"; (bag) "Rogers Hi Five * * * Range Cake Manufactured by Rogers Products Company, Ainsworth, Nebr."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 31.8 percent of the declared amount of diethylstilbestrol. The article had been manufactured locally by the dealer, Rogers Grain & Feed, from a premix shipped as above.

LIBELED: 6–9–64, Dist. Nebr.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess.

The libel alleged also that the article was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 8–4–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7983. Slendron capsules. (F.D.C. No. 48427. Inj. No. 468. S. No. 39–148 V.)

QUANTITY: 24 unlabeled ctns. containing a total of 117,500 capsules, at New York, N.Y., in possession of Tops Products Co., which firm in the normal course of business operations would pack the article, for Bio-Tech Products Co., Brooklyn, N.Y., into 100-capsule jars labeled as described below.

SHIPPED: 9–20–62, from Elizabeth, N.J.

LABEL IN PART: (Jar) "Slendron Distributed by Bio-Tech Products Co., Brooklyn, N.Y. Directions: As a food supplement * * * Ingredients: Each Capsule Contains Safflower Oil 750 mg. B_6*–5 M.G. Linoleic Acid 510 M.G."

ACCOMPANYING LABELING: Folder entitled "The Slendron Plan" and jar labels.

RESULTS OF INVESTIGATION: The folders were printed locally on order of Bio-Tech Products Co.

LIBELED: 12–19–62, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the name "Slendron" and statements in the labeling of the article falsely and misleadingly represented and suggested that the article was adequate and effective for the treatment of obesity and to maintain a slender figure without regard to the total caloric content of foods consumed, and for the control of the appetite; and that the article was of unusual significance for special dietary supplementation by reason of the presence therein of safflower oil and linoleic acids.

DISPOSITION: On 1–21–63, Al Marvin, d/b/a Bio-Tech Products Co., appeared as claimant and filed an answer denying that the article was misbranded. On or about 2–12–63, the claimant served written interrogatories on the Government which were answered on or about 2–26–63. On 6–6–63, the case came on for trial before the court.

On 6–10–63, on the motion of the Government and after hearing evidence introduced at a trial and hearing held on 6–6–63 and 6–7–63, and having

*See also Nos. 7941, 7944, 7953, 7954, 7960, 7961, 7964–7972, 7974–7978.

examined the Government's exhibits in evidence, and having found that the article was mislabeled by (a) its name, (b) a pamphlet, "The Slendron Plan," and (c) its label which included the depiction of a slender female form, and hence was misbranded, the court ordered that, until the determination of the Government's prayer for a permanent injunction, the claimant was enjoined from shipping into interstate commerce or from holding for sale after such shipment, any article of drug accompanied by the labeling described above or which made the same or similar representations or suggestions, and which failed to bear adequate directions for use.

On 6–27–63, the court rendered the following findings of fact and conclusions of law:

PALMIERI, *District Judge:*

FINDINGS OF FACT

"(1) On December 19, 1962, a libel of information was filed by the United States and asked for the seizure for condemnation of an article of drug pursuant to 21 U.S.C. § 334(a), alleging that the article was misbranded within the meaning of 21 U.S.C. § 352(a). In the libel, the relief prayed for was (1) that the court issue a process of attachment; (2) that the article be condemned and sold or otherwise disposed of; (3) that the court award costs to libelant; and (4) that libelant have such other and further relief as the nature of the case may require. At trial, a motion to amend the libel to include a specific prayer for injunctive relief was granted (Tr. 222).

"(2) Seizure of the libeled articles was effected on December 21, 1962, by a United States Marshal (Tr. 25). The articles seized included 117,500 capsules packaged in bulk cartons, of an article of drug called 'Slendron', and fifteen 100-capsule bottles of an article of drug labeled in part 'Slendron', and approximately 6,000 folders entitled 'The Slendron Plan.'

"(3) Seizure took place on the premises of Tops Products Company, 203 East 12th Street, New York, New York. The goods seized were those described in the libel (Tr. 25).

"(4) Each Slendron capsule contains 750 mg. of safflower oil and 5 mg. of vitamin B_6 (Libelant's Exh. 2).

"(5) On January 21, 1963, Al Marvin, d/b/a Bio-Tech Products Co. ("Bio-Tech") filed a claim of owner and prayed to defend accordingly. His answer was filed the same day.

"(6) The article of drug above described was shipped in bulk by Pharmacaps, Inc. (manufacturer) of Elizabeth, New Jersey, via the shipper's trucks to Warner Laboratories in Brooklyn.

"(7) Warner Laboratories reprocessed the capsules and then shipped them to Tops Products Company (Tr. 28; Libelant's Exh. 15).

"(8) Tops Products Company packages and labels the product for Bio-Tech Products Co. (Tr. 41), enclosing a label (Libelant's Exh. 2), in each jar. These jars or bottles each contain 100 capsules.

"(9) A folder entitled 'The Slendron Plan' (Libelant's Exh. 1), and a business reply envelope (Libelant's Exh. 2a), and the bottled capsules (Libelant's Exh. 3) are then placed in mailing cartons and address label and postage are affixed (Libelant's Exh. 4, 4a).

"(10) The address label is supplied by Bio-Tech (Tr. 41).

"(11) Orders for 'Slendron' are solicited by mail by Bio-Tech (Libelant's Exh. 5, 16).

"(12) Prospective purchasers send a coupon to Bio-Tech at 721 Rockaway Avenue, Brooklyn. The address labels are presumably prepared from this coupon. However, 721 Rockaway Avenue is merely the address of a telephone answering service and mail drop (Tr. 37). 'Slendron' is not processed in any way at this address.

"(13) The volume of sales solicited in this manner and prepared for shipment by Tops Products Company is indicated by invoices to Bio-Tech from Tops Products (Libelant's Exh. 14). These show that as many as 2,500 bottles have been shipped in a single month and that substantial shipments were made as late as May 28, 1963 (Tr. 221).

"(14) At the time of seizure, a supply of the pamphlet 'The Slendron Plan' was located within fifteen feet of a supply of capsules (Tr. 26) which, in the normal course of business, would be labeled by the 'Slendron' label and packed together with 'The Slendron Plan' for shipment to the ultimate consumer (Tr. 41).

"(15) This consumer, in many cases, had previously received an advertisement, 'N.Y. Doctor Conquers Fat Problem! ! !' (Libelant's Exh. 5).

"(16) 'The Slendron Plan' is stated to be 'For The Normal Healthy Person Who Is Concerned With His or Her Health and Appearance.' It includes these statements:

> The Slendron Plan, and Slendron itself, is designed to help you lose weight as simply and as quickly as possible. If you are in normal health and your weight problem is not due to a glandular condition, then Slendron will help you.* Read this plan carefully, follow the directions, and you should be pleased with the results. But first you must understand a few facts, and learn how and why Slendron is the latest, most up-to-date way of losing weight based on the latest medical and scientific research.
>
> Slendron capsules can help in reducing obesity, but they alone are not enough to rid you of all your excess weight. But taking the capsules and following the plan will. The plan is based on three principles.
>
> Firstly, you should never feel hunger. Never walk away from a meal with your appetite unsatisfied. If you're hungry between meals, eat. It's not how much you eat, or when you eat it that counts. It's what you eat—and that brings us to the second principle.
>
> Keep your intake of carbohydrates at an absolute minimum. This means you must stay away from starches and sugars. But you can eat as many high protein foods as you want. And you should eat as much food rich in fat—particularly foods rich in unsaturated fatty acids like fish, other seafood and most cheeses—as you can. Eating these foods, as we have seen, spurs the metabolism on to shed fat from the body—.*
>
> Don't worry about taking in too much fat. Your body will let you know when you have had enough. (The sign of eating too much fat is nausea.)
>
> Have fried foods every day.*
>
> You must have three full meals at regular intervals each day; do not leave the table hungry.
>
> Do not add salt to your food.
>
> Here are the foods to shun. They must be shunned absolutely. You cannot eat even small amounts of them without greatly impeding your weight loss.
>
> 1. Fruits containing more than 5 per cent carbohydrates.
> 2. Fruit juices of all kinds.*
>
> These, then are the foods you may eat as you begin adopting this new nutrition principle, you will agree that it is a wide list. Since it is important for you to eat large quantities of fish and meats, you will not go hungry. I[n] fact, you may have to eat more than you have been eating.

"(17) In the advertisement 'N.Y. Doctor conquers Fat Problem! ! !' the following claims appear:

> EAT RICH-FRIED FOODS and LOSE UP TO 15 POUNDS IN 14 DAYS. NEW MEDICAL DISCOVERY PROVES DROPPING CALORIES DOESN'T NECESSARILY DROP WEIGHT. INSTEAD LOSE WEIGHT WHILE YOU EAT FRIED CHICKEN, FRIED POTATOES, FRIED FISH, FRIED SHRIMP, PIE CRUST, ETC.
>
> *Calories don't count. In fact, you must eat fat to stay slim.
>
> *"carbohydrates commit the weight crime . . . not calories."
>
> *special Natural substances (with long names) work wonders in the body. They team up perfectly and naturally with your normal body functions. and do many things for you. These special substances (which we blended together and call SLENDRON) help your body release more energy, and stop you from feeling hungry so often. MORE IMPORTANT, SLENDRON SQUEEZES FAT RIGHT OUT OF YOUR BODY.*

SLENDRON ,THE NEW MEDICAL MARVEL, DOES YOUR WORK FOR YOU. It does it with absolute safety because SLENDRON is a combination of Nature's own properties. Use it and you can eat while you lose.

"(18) The 'Slendron Plan' was used to promote the sale of 'Slendron' capsules and to explain their use.

"(19) In sum 'The Slendron Plan' suggests that weight may be lost without regard to the total number of calories consumed and that Slendron capsules contain ingredients which will spur weight reduction.

"(20) The Slendron Plan is virtually identical with the weight reduction scheme in 'Calories Don't Count' by Dr. Herman Taller (Libelant's Exh. 13; Tr. 218).

"(21) Libelant presented two eminently qualified experts in the field of human nutrition as expert witnesses.

"(22) Dr. Fredrick J. Stare is Chairman of the Department of Nutrition at Harvard University; the author of some 250 articles in the field of nutrition, biochemistry and chemistry. He holds a degree in medicine and doctorate in biochemistry. He teaches at Harvard Medical School and regularly conducts post-graduate seminars for doctors at Massachusetts General Hospital (Tr. 44–47). Dr. Stare testified categorically that if 'The Slendron Plan' were followed explicitly and the capsules taken as directed they would not provide an adequate and effective means of losing weight (Tr. 51, 139).

"(23) He was emphatic that the capsules had no value as a food supplement in the diet of a normally healthy person (Tr. 52); at best they are innocuous.

"(24) Dr. Stare testified that the only accepted basis for reducing weight is for the individual to consume less calories and expend more calories (Tr. 49, 68, 77, 145).

"(25) Dr. Stare testified that there is no evidence of a difference in the metabolism of obese individuals insofar as the utilization of carbohydrates or fats is concerned (Tr. 79–81, 95).

"(26) Dr. Stare further testified that if the total number of calories in a diet were such that weight loss could be accomplished, the respective proportion of fat, protein and carbohydrate in the diet is immaterial (Tr. 89, 140).

"(27) Dr. George J. Christakis is the director of the Bureau of Nutrition, Department of Health, City of New York, and a professor of clinical nutrition (Tr. 147). He has extensive experience in the clinical treatment of obese patients (Tr. 148a).

"(28) Dr. George J. Christakis' testimony corroborated Dr. Stare's. (Tr. 149–150, 155, and passim.)

"(29) Dr. Christakis also asserted that the dietary plan described in 'The Slendron Plan' is a matter of public health concern (Tr. 150, 167), and contains many principles which are medically unsound.

"(30) Dr. Christakis criticized any weight reduction plan which drastically restricts the intake of carbohydrates, of fruits, vegetables and cereals (Tr. passim).

"(31) He thought that 'The Slendron Plan' if followed, would lead to a deficiency of vitamin E in the diet and deficiencies of vitamins A, C and Thiamine (Tr. 153, 196–197).

"(32) Dr. Christakis also asserted that the proportion of fat in the 'Slendron' diet was too high for many people and would result in the condition of ketosis or acidosis (Tr. 154). In sum, Dr. felt that the Plan was medically inadvisable.

"(33) As to whether weight could be lost on this plan, Dr. Christakis testified that weight reduction depends on caloric balance (Tr. 149), and that to feel hunger is a natural concomitant of a weight loss program (Tr. 190).

"(34) The doctor testified that it was misleading to suggest that diet alone would result in the pleasing silhouette of the young lady on the 'Slendron' label (Tr. 198–200).

"(35) He also testified that no effective weight-reducing plan could depend on (a) never being hungry and (b) eating all the fried foods wanted (Tr. 211).

"(36) The claimant did not refute any of the medical testimony offered by libelant. No expert testimony was offered [in] behalf of the claimant.

"(37) The testimony of libelant's expert witnesses was marked by candor. I accept their entire testimony as being truthful.

"(38) It appears from claimant's course of conduct since the libel was filed (Libelant's Exh. 14), that he will continue to violate the Federal Food, Drug, and Cosmetic Act, unless enjoined and restrained by Order of this Court.

"(39) At the time of seizure, each bulk carton had affixed to it the Slendron label above identified as libelant's exhibit 2 (Libelant's Exh. 15).

"(40) On the basis of the testimony of Dr. Stare and Dr. Christakis, and libelant's exhibits in evidence, I find that the name Slendron and statements in its labeling, namely, the repack label and the carton insert, 'The Slendron Plan,' represent and suggest that Slendron is adequate and effective for the treatment of obesity and to maintain a slender figure without regard to the total caloric content of foods consumed; and for the control of the appetite; and that the article of drug is of unusual significance for special dietary supplementation by reason of the presence therein of safflower oil and linoleic acid. I further find on the basis of the testimony of Drs. Stare and Christakis that Slendron is not adequate and effective for these purposes.

CONCLUSIONS OF LAW

"1. This Court has jurisdiction over the res, 21 U.S.C. § 334, and over the claimant. *Hipolite Egg Co.* v. *United States*, 220 U.S. 45, 60 (1911); *United States* v. *184 Barrels Dried Eggs*, 53 F. Supp. 652, 654 (E.D. Wis. 1943).

"2. The libelant has met its burden of demonstrating misbranding of a drug, by reason of labeling which is false or misleading in some particular. 21 U.S.C. § 352(a). *United States* v. *47 Bottles, More or Less, Jenasol RJ Formula 60*, 200 F. Supp. 1 (D.N.J. 1961).

"3. All of the capsules seized, including those packed in bulk, 21 U.S.C. § 353(a), are misbranded.

"4. The misbranding lies in labeling which is false or misleading. 21 U.S.C. §§ 321(k), 352(a).

"5. The printed matter seized with the article of drug is labeling within the meaning of 21 U.S.C. § 321(m).

"6. The name 'Slendron' and the female figure on the label are similar labeling. *United States* v. *Fifteen Cartons, More or Less, of Sekov Reducer*, 45 F. Supp. 52 (S.D. Tex. 1942); *Sekov Corp.* v. *United States*, 139 F. 2d 197 (5th Cir. 1943).

"7. The advertisement 'N.Y. Doctor Conquers Fat Problem!!!' is probative of the intent of the labeling. *United States* v. *39 Bags, More or Less, Elip Tablets*, 150 F. Supp. 648, 650 (E.D.N.Y. 1957).

"8. The labeling is false or misleading in that it represents or suggests that Slendron capsules, or the capsules in conjunction with the Slendron Plan, are adequate and effective for the treatment of obesity and to maintain a slender figure without regard to the total caloric content of food consumed, for the control of appetite, and that Slendron is of unusual significance for special dietary supplementation, whereas, in fact, they are not adequate and effective for such purposes and have no such significance.

"9. Tops Products Co. is a repacking establishment within the meaning of 21 U.S.C. § 353(a).

"10. A decree of condemnation shall be entered against the articles under seizure which shall direct their destruction. 21 U.S.C. § 334(d).

"11. Costs shall be awarded to libelant. 21 U.S.C. § 334(e).

"12. Al Marvin, doing business as Bio-Tech Products Co., has caused to be introduced and delivered for introduction in interstate commerce, and has held for sale after shipment in interstate commerce, a misbranded drug in violation of 21 U.S.C. §§ 331(a) and (k).

"13. Libelant's prayer for relief in its libel is broad enough to include the injunctive relief herein sought.

"14. Claimant shall be enjoined from introducing and causing to be introduced or delivering and causing to be delivered for introduction into interstate commerce, or holding or causing to be held for sale after shipment in interstate commerce, any such article of drug accompanied by labeling as described above or which makes the same or similar representations or suggestions. *United States* v. *47 Bottles, More or Less, Jenasol RJ Formula 60*, 201 F. Supp. 915 (D.N.J. 1962); *United States* v. *184 Barrels Dried Eggs*, 53 F. Supp. 652 (E.D.Wis. 1943). Compare *United States* v. *Nysco Labs., Inc.*, No. 28171, 2d

Cir., June 7, 1963 (determination as to "false and misleading" issue in seizure action *res judicata* in second action seeking injunction).

"15. Claimant shall be required to give written notice of the provisions of this decree to each and all of its present and future officers, agents, servants, employees and representatives, and all persons now or in the future in active concert or participation with them or any of them who shall, upon receiving actual notice, be similarly enjoined. Rule 65(d), Fed. R. Civ. P.

"Submit proposed judgment on notice."

On 7–8–63, a final decree of injunction was filed which read, in part, that the libelant having moved, under the general prayer for relief in the libel heretofore filed and by motion made at trial on 6–7–63, for an injunction, and the court having considered the evidence, and it appearing that the claimant would continue to violate the Federal Food, Drug, and Cosmetic Act by causing to be introduced and delivered for introduction into interstate commerce, and by holding and causing to be held for sale after shipment in interstate commerce, drugs which are misbranded within the meaning of 502(a) or which may be misbranded within the meaning of 502(f)(1), unless restrained by Order of this court; it is therefore

ORDERED, ADJUDGED, and DECREED that an injunction was granted, and that AL MARVIN, an individual, doing business as BIO-TECH PRODUCTS COMPANY, and all other persons in active concert or participation with him were enjoined and restrained from, directly or indirectly, introducing and delivering for introduction and causing to be introduced and delivered for introduction into interstate commerce, and holding or causing to be held for sale after shipment in interstate commerce, the drug designated by the name "*Slendron*" or the same drug by any other designation, or any similar drug, which:

(1) was accompanied by the label, reading in part, "100 Capsules Slendron Distributed by BIO-TECH PRODUCTS COMPANY" or by the pamphlet entitled "The Slendron Plan" or any similar written, printed, or graphic matter, or any other written, printed, or graphic matter which contained statements which represented or suggested that "*Slendron*" *capsules* were adequate and effective for the treatment of obesity and to maintain a slender figure without regard to the total caloric content of foods consumed; or for control of the appetite; or that the article was of unusual significance for special dietary supplementation by reason of the presence therein of safflower oil and linoleic acid; or which contained any other false and misleading statement, or

(2) failed to bear or be accompanied by labeling which states each and every purpose and condition for which such capsules are intended to be used, together with sufficient information to enable the layman to use the capsules safely, intelligently, and effectively for each such purpose and condition, or in any other manner failed to bear adequate directions for use.

On 7–8–63, a decree of condemnation was filed with respect to the article seized, which decree provided that the Government should recover, against the claimant, court costs and fees, storage, and other proper expenses, and provided that 15 jars of capsules, 2 bulk cartons, 100 copies of "The Slendron Plan," and the bulk carton marked "Libellants Ex 15" should be delivered to the Food and Drug Administration, and that the balance of the seized capsules, together with all remaining literature seized with the capsules, be destroyed.

On or about 8–27–63, the claimant moved to retax and strike out certain costs assessed against the claimant; and on 9–30–63, the court rendered the following opinion:

PALMIERI, *District Judge:* "This is a motion by claimant to retax and strike out the item of $274.50 allowed as costs by the clerk. This item is made up of fees paid to the court reporter for the cost of the trial transcript.

"The claimant urges that the transcript was obtained solely for the libelant's convenience and without any order from the trial court. Admittedly, the taxation of these costs is a matter of discretion. *Perlman* v. *Feldmann*, 116 F. Supp. 102 (D. Conn. 1953). While it is true that there was no direction by the trial court for the submission of the transcript, it became necessary to file findings of fact and conclusions of law and the transcript was referred to over thirty times in the findings of fact. The decision of the Court in this case could not have been made without the use of the transcript. The test of reasonable necessity of the transcript for use by the Court has been met and it follows, therefore, that the allowance of the costs in question was properly made by the clerk. 28 U.S.C. § 1920(2); *United States* v. *Arthur N. Olive Co.*, 30 F.R.D. 139 (D. Mass. 1962); *Modick* v. *Carvel Stores of New York, Inc.*, 209 F. Supp. 361 (S.D.N.Y. 1962).

"The motion is denied. It is so ordered."

On 11–15–63, pursuant to the decree of condemnation, 15 jars of capsules, 2 bulk cartons, 100 copies of "The Slendron Plan," and the bulk carton marked "Libellants Ex 15" were delivered to the Food and Drug Administration; the remainder of the article was destroyed.

7984. CDC capsules. (F.D.C. No. 46938. S. Nos. 39–997 T, 40–469 T.)

QUANTITY: 40 cases, each containing 8 ctns. of 6 84-capsule btls. each; 35 cases, each containing 8 ctns. of 12 42-capsule btls. each; 46 cases, each containing 10 ctns. of 12 42-capsule btls. each; 7 cases, each containing 12 ctns. of 12 42-capsule btls. each; 4 cases, each containing 4 ctns. of 6 200-capsule btls. each; 61 cases, each containing 3 ctns. of 12 42-capsule btls. each; and 125 cases, each containing 2 ctns. of 6 200-capsule btls. each, at Brooklyn, N.Y., in possession of Cove Vitamin & Pharmaceutical, Inc.; and 189 42-capsule btls., 123 84-capsule btls., and 50 200-capsule btls., at Brooklyn, N.Y., in possession of a customer of Cove Vitamin & Pharmaceutical, Inc.

SHIPPED: Between 11–16–61 and 12–26–61, from Clifton, N.J., by Cove Vitamin & Pharmaceutical, Inc.

LABEL IN PART: (Btl.) "CDC Capsules For Use As Directed With The CDC Calories Don't Count Weight Control Program A Product of Cove Vitamin & Pharmaceutical, Inc. Glen Cove, New York. Directions: * * * Ingredients: Each CDC Capsule Contains 912 mg. of Safflower oil and 0.5 mg. of Vitamin B–6.* Each capsule contains 95% fat from Safflower oil. Calorie content per capsule 8.2 * * * Safflower oil provides a supplementary source of polyunsaturated fatty acids essential to the C-D-C Weight Control Program."

ACCOMPANYING LABELING: Booklets entitled "The CDC 'Calories Don't Count' Weight Control Program * * * Following are excerpts from the book 'Calories Don't Count,' by Dr. Herman Taller, New York"; window streamers and placards reading in part "We've Got It! CDC capsules 'Calories Don't Count'" and containing pictures of the book and the article; and books entitled "Calories Don't Count," by Herman Taller, M.D.

LIBELED: 1–23–62, E. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the control of body weight, and to reduce and maintain slimness even though consuming many thousands of calories daily without regard to the total caloric intake, to lower and control the cholesterol level of the blood, for the treatment and prevention of arteriosclerosis and heartburn, and to improve the complexion, increase resistance to colds and sinus trouble, promote health, and increase sexual drive.

Disposition: The article was claimed by Cove Vitamin & Pharmaceutical, Inc., Glen Cove, N.Y. The claimant filed written interrogatories on 2–16–62, and on 2–28–62, moved for partial summary judgment which motion was argued on 3–7–62 and denied on 3–21–62, with the following opinion (204 F. Supp. 280):

Dooling, *District Judge:* "Claimant moves for summary judgment on the issues tendered by so much of the libel of information (21 U.S.C.A. § 334(a)) as alleges that claimant's CDC capsules were 'misbranded' (21 U.S.C.A. § 352 (a)) in that their 'labelling'—which is alleged to include, as 'printed or graphic matter' 'accompanying' the article, Taller's book 'Calories Don't Count' (21 U.S.C.A. § 321(m)(2))—represents and suggests that the article is adequate and effective 'to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis and heart burn; and to improve the complexion; increase resistance to colds and sinus trouble; promote health; increase sexual drive; and for other purposes'.

"Claimant agrees that Taller's 'Calories Don't Count' 'is, in part, labeling for the claimant's product insofar as claimant refers to the weight control program of that book and the dietary instructions contained therein.' Claimant contends that by its product's label, container, enclosed booklet and all of its advertising materials it has invoked only the Taller weight control program as given in Taller's book and that these limited references preclude any claim that any other part of Taller's book, and especially his assertion of the therapeutic value of weight control, constitutes 'labelling' of its CDC capsules. Claimant emphasizes that Taller's book is in its own right a 'best seller', published by an unaffiliated publisher of standing and is not sales literature produced and circulated by claimant. It argues that if limited references to books that are independent of the drug in their provenance are treated will-nilly as adopting all parts of the book as 'labelling', absurdities follow inevitably, including constructive adoption of contradictions, irrelevancies, and disclaimed assertions.

"Claimant agrees that if Taller's book in its entirety is 'labelling' of the capsules, there is a triable issue of fact on the correctness of the assertions singled out by the libellant. The question, therefore, is whether claimant has demonstrated beyond factual controversy that Taller's book is 'labelling' of claimant's product to the extent only of the book's statement of the weight control program, for it does not appear to be argued that it is possible on the present motion to establish any limit to the 'label' short of the whole book if claimant's limitation of its references to Taller's 'Weight Control Program' are not shown on the present evidence to delimit the part of the book that is 'labelling'.

"Libellant denies the possibility that less than the whole book can be labeling if any significant part of the book is labeling and maintains in any case that claimant's references can not determine how much of the book is labeling but only objective fact and the effect of the material on consumers.

"The intentional association of the capsules with at least part of the book is plain and conceded. The package of the capsules uses the color scheme of the cloth binding of the book. The title of the book is inserted on the paster label and cardboard container of the capsule bottle to explain the reference to the 'CDC Weight Control Program'. The pamphlet inserted in each container of pills gives under the letters 'CDC' the title of the book in quotation marks and bears a background photograph of the book in its dust jacket. The pamphlet states that it is made up of excerpts from the book and adds, by footnote to a reference to Taller's recommended reducing program, the sentence 'For a detailed description of this program, we suggest you read the entire book.' In the first of the series of newspaper advertisements presented, Taller and his program are discussed. In the second, the book itself is advertised for sale on the same page as the capsules. The fourth advertisement does not refer to Taller but to a 'well-known doctor' and counsels purchase of CDC capsules 'to make sure you have the same capsules used by this well-known doctor in his work'. Taller at page 21 refers to a three ounce daily dosage of an oily substance prescribed to him by a 'research' which alleviated his cholesterol count and occasioned loss of weight and he states, of his daily dose of the oily substance, '(Recently developed capsules have made the routine easier.)' At page 151 Taller lists safflower oil as highest in percentage content of linoleic

acid, and he states, at page 152, that linoleic acid is clearly the most valuable of the unsaturated fats and that it 'is becoming more easily available, both in liquid form and in capsules obtainable at drug and department stores or through such mail-order sources as Cove Pharmaceuticals', evidently meaning claimant, though that is not its correct name. Taller says (p. 152) that the easiest routine is to take two capsules before each meal and refers to capsules of safflower seed that contain vitamin B–6, 'a valuable factor in the burning of fatty tissue'. Claimant's capsules are to be taken two before each meal and the ingredients are safflower oil and vitamin B–6. A window sticker, supplied by claimant to merchants, depicts a package of claimant's article opposite a copy of Taller's book in its dust jacket. One merchant is shown to have mounted a display of the article and a poster picturing the article and the book and stating 'Book Available in Our Book Dept. On The Mezzanine'.

"The limitations on the adoption of the Taller book are, on this record, at best implied; there is no express disclaimer of any part of the Taller book and the references to it are not shown on this record to be such as to restrict the buyer's attention to any specified pages in the book. Nowhere is there shown to be rejection of anything Taller says; there is the suggestion, on every package, that the capsule buyer read the entire book.

"The claimant's own sales literature makes no direct claims of the kind involved in this motion;[1] the keynote of the reference to Taller is 'Calories Don't Count—Weight Control Program'. No particular section of Taller's book has such a title or heading. The chapter entitled 'Your "Diet"' (pp. 136–157) is the one excerpted in the pamphlet contained in each container of capsules and is characterized thus by Taller; 'This, in a sense, is your reference chapter, one to keep reviewing and to keep studying, for it tells you how to put my new nutrition principle into practice.' This chapter contains typical questions and Taller's answers; one pair reads:

> Q. Will the diet have any beneficial effects aside from getting rid of fat?
> A. Your general disposition and outlook may improve, because you are nourishing your body properly. Your complexion may improve. You will be less likely to suffer from heartburn. You may experience an increased sexual drive. (These improvements have all been reported to me by many of my patients.)

"Adopting claimant's theory, it is not feasible to sort out the 'Your "Diet"' chapter of Taller as between the adopted and the rejected. The adoption would not, it seems, be limited to what is quoted in the pamphlet; certainly, on claimant's theory, it would extend to the discussion of safflower oil and to the references to 'Cove Pharmaceuticals' and to the safflower oil-vitamin B–6 capsules. Adoption cannot, it seems, on claimant's theory as presented on this motion, stop short of page 153, line 7. Line 8, however, reads, ' I think this is a chapter you may want to read several times.' The next paragraph commences, 'Of course you have questions.' Lower on the page start the typical questions and answers (one pair of which is quoted above) followed by the closing statement that, 'This, in a sense, is your reference chapter'.

"Claimant's contention understates the apparently intended unity of Taller's book. Taller does not profess simply to supply a workable weight-reducing program. He argues broadly that obesity is a threat to health, that the supposedly traditional modes of alleviating it are ineffective, unscientific and potentially dangerous to health, and that the program he recommends, and the supposed biochemical basis of which he outlines, will control weight and in reasonable likelihood produce a range of beneficial side-effects. Taller's book is not self-divided; it could be divided, although not easily, into background and theory, program and benefits, but no division is invited by Taller and claimant's direct advertising literature, as produced on this motion, does not counsel that but suggests reading the entire book.

"Since claimant's motion depends absolutely on showing beyond substantial factual controversy that the Taller book is invoked as labeling only in a de-

[1] On the window sticker, picturing the Taller book, it is possible to read the dust jacket assertion that weight loss links to "a low cholesterol count, better skin condition and resistance to cold and sinus trouble." Claimant says consumers could not read this when the sticker is on normal display.

finable part that excludes the statements relied on by libellant, the motion must be denied for failure to show on this motion that the advertising material relied upon delimits beyond reasonable controversy the part less than the whole of Taller's book that constitutes labeling. The record made on this motion supports as a permissible inference of fact that adoption of the book is unlimited.

"The motion, so far as framed under Fed. Rules Civ. Proc. Rule 12, 28 U.S.C.A. rather than Rule 56, could present the issue no more advantageously to claimant, if the motions under Rule 12 are considered available to claimant at this stage of the case and in the form presented.

"Accordingly claimant's motions are in all respects denied.

"It is so ordered."

Answers to the claimant's interrogatories were filed on 4–4–62. On 4–23–62, the court denied the claimant's motion for summary judgment and delivered the following opinion (240 F. Supp. 283):

DOOLING, *District Judge:* "Claimant moves for summary judgment on the ground that the libel charges that the misbranding of claimant's safflower oil and vitamin B–6 capsules consisted in representing that the product itself was efficacious as a weight reducing agent whereas, claimant contends, as a matter of indisputable fact the capsule was labelled only as a supplement for use with the CDC Weight Control Program.

"It has been concluded, on an earlier motion, that there is an issue of fact concerning the extent to which matter contained in Taller's book 'Calories Don't Count' has been incorporated as 'label' on claimant's product. That conclusion complicates the task of isolating the present issue because it suggests that matter which is 'label' and located in Taller's book could be advanced by the libellant as at least arguably, claiming directly remedial effect for the capsules. Taller's pervading insistence is that such a polyunsaturated fatty acid as safflower oil functions, as a matter of body chemistry, to dispose of certain fatty tissue; he argues (and the pamphlet, accompanying each lot of capsules, repeats) that meals must not be omitted, that the patient should force himself to eat at least some food containing polyunsaturated fat and should not worry about ingesting too much fat since the sign of eating too much of it is nausea. A permissible inference from the urging to eat polyunsaturated fatty acids even to the point at which they nauseate is that they are presented not as dietary supplements but as a specific for weight reduction (or, more accurately, for reduction in girth). Taller's recital of his own experience of amelioration when he added an intake of polyunsaturated fatty acids to his customary diet makes his point with neat impressiveness.

"Assuming that exactly what has been represented is factually controversial to the extent that it depends on determining how much of Taller's book shines through the formal label of the capsules, does the affirmative language choice of the label and advertisements remove whatever claims are made from the product itself and fasten those claims on the 'CDC Weight Control Program' as a distinguishable thing and on it alone, so that it can be said that the claims are not made for the capsules, which alone are charged with being misbranded?

"The pamphlet enclosed in each package of CDC capsules is explicit that CDC capsules are to be taken before each of the three daily meals that must be eaten. The dietary commands are of triple aspect: eat foods that contain proteins and polyunsaturated fatty acids; avoid foods that are high in carbohydrates; within the foregoing principle of selection, ignore quantitative measures of caloric intake. The more detailed instructions discriminate kinds of fats; visible meat fat is to be cut away and the vegetable oils are to be used in cooking; fish or seafood the patient is to make sure he eats once a day, because they are rich in polyunsaturated fatty acids.

"The formal label of the CDC capsules directs that two capsules be taken before each meal. This is followed by the sentence 'For *additional* information and suggested menus to *help* you lose weight with the CDC Weight Control Program refer to the enclosed booklet . . .' (Italics added.) The choice of language, however, inadvertent to the point, might suggest that primacy of importance attaches to taking the capsules and that the rest is additional and helpful rather than central. The 'ingredients' statement discloses that each capsule holds 912 mg. of safflower oil and that 'safflower oil provides a supple-

mentary source of polyunsaturated fatty acids essential to the CDC Weight Control Program.' The pamphlet, with its emphasis on the importance of consuming foods rich in polyunsaturated fatty acids without regard to quantity (as contrasted to the rigorous ban on carbohydrates and the disapproval of the most obvious of fats, the visible fat on meat), assigns a special and necessarily remedial role to the polyunsaturated fatty acids of which safflower oil is stated on the package to be one.

"The New York Times advertisement of January 21, 1962 states, 'In fact, a well-known doctor advocates that to get rid of excess fat, you must eat three full meals a day, *and you must consume more fats* of a very special kind. These are the polyunsaturated fats.' (Words italicized in original.) After referring to the CDC plan as a 'new bio-chemical' concept of weight control, the advertisement characterizes as the plan's cornerstone 'a radical new diet pattern that calls for plenty of fats, preferably polyunsaturated fats.' After a sub-headline reading 'Polyunsaturated fats essential', the copy continues, 'And because it is sometimes difficult for people accustomed to large amounts of fats in the diet to take in each day the quantities of fats called for, the CDC plan provides you with polyunsaturated fats in convenient capsule form to supplement your meals.' It is further on said, 'The combination of CDC capsules and the CDC weight control program is designed to help you lose excess fat . . .' A sub-headline of the advertisement reads: 'The more fat you eat, the more fat you lose!'

"If the claims were meant to attach to the program and not to the product the intention failed of execution. The essence of the whole is that the capsules are, in concentrated form, the polyunsaturated fatty acid that is the true specific for burning off body fat that has been lacking in all previous calorie-counting diets, or so, certainly, on the facts a jury could reasonably find. The capsules alone are not held out as all sufficient, nor heavy consumption of foods rich in polyunsaturated fatty acids; but the representation may properly be found to be that the capsules specifically will as a matter of bio-chemistry function to dispose of fatty tissue because they contain polyunsaturated fatty acids; whether reduction in weight or girth follows is plainly enough made to depend on whether carbohydrates are sufficiently eliminated from the diet; but the ameliorative role specifically assigned to the polyunsaturated fatty acids, and therefore to the CDC capsules of safflower oil, is indelibly part of the representations.

"Supposing that the CDC capsules were represented only as integral to a regimen for which the broader claims were made, the broader claims would nevertheless be part of the labelling of the capsules. Few remedies operate outside a regimen and if a substance is the defining element of a regimen, what is said of the regimen is said of its characterizing element. So here; the regimen is characterized by consumption of polyunsaturated fatty acids; that is the differentiating and defining element; the CDC capsules are, in concentrated form, that element and a label-prescribed part of the regimen; what is said of the regimen is said of the CDC capsules. *Colusa Remedy Co.* v. *United States*, 8th Cir. 1949, 176 F. 2d 554 and *Bradley* v. *United States*, 5th Cir. 1920, 264 Fed. 79 imply as much if, not having to, they do not go just that far.

"It is concluded that the motion for summary judgment must be, and it is, denied.

"It is so ordered."

On 4–30–62, the claimant moved for the production of documents in possession of the Government and to compel further answers to interrogatories.

During May and June 1962, the Government took the deposition of Dr. Herman Taller and others, and on 6–15–62, the Government moved for an order to Show Cause Why The Witness [Dr. Taller] Should Not Be Held in Contempt of Court for failure to answer.

Subsequently, the claimant withdrew its claim and answer on 6–19–62, and on 6–27–62, a default decree was entered condemning the article and ordering its destruction with the accompanying labeling, except for the copies of the book "Calories Don't Count" by Herman Taller, M.D., which were released to the Food and Drug Administration, and further ordering that the claimant be taxed costs.

7985. Amphaplex Injectable. (F.D.C. No. 49634. S. No. 94–531 V.)

QUANTITY: 278 individually ctnd. 10-cc. vials at Columbia, S.C.

SHIPPED: 4–17–62, from Brooklyn, N.Y., by Obetrol Pharmaceuticals Div., Rexar Pharmacal Corp.

LABEL IN PART: (Vial) "Multiple Dose Vial Amphaplex Injectable For Subcutaneous Use See Box label and Insert Palmedico, Inc. Columbia, S.C. Distributors," (ctn.) "Amphaplex (Injectable) * * * Sole Distributors Palmedico, Inc. * * * Columbia, S.C. As an adjunct in obesity therapy. For subcutaneous injection. Usual Dose: * * * Caution * * * Each cc. contains in injection water: Methamphetamine Potassium Saccharate 10 mg., Amphetamine Potassium Saccharate 5 mg., Amphetamine Ascorbate 8.15 mg."

ACCOMPANYING LABELING: Inserts entitled "Ampheplex (Injectable) Composition * * * Actions and Indications * * * Side Effects * * * Precautions and Contraindications * * * Palmedico, Inc. * * * Columbia, S.C."

LIBELED: 12–16–63, E. Dist. S.C.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that a single 0.5-cc. subcutaneous injection once a week would adequately control the appetite for inducing weight reduction in the management of obesity.

DISPOSITION: 1–30–64. Default—destruction.

7986. Chocolate-flavored wafers. (F.D.C. No. 49096. S. No. 22–611 X.)

QUANTITY: 757 cases, each containing 48 pkgs. of 100 wafers each, at Salt Lake City, Utah.

SHIPPED: 3–21–63 and 4–8–63, from Los Angeles, Calif., by Custom Packaging Co.

LABEL IN PART: (Pkg.) "Lyfft Quick Energy Food Chocolate Flavored * * * Manufactured for Lyfft Distributors, Inc., Salt Lake City, Utah * * * A Concentrated Energy Food Wafer, Composed Entirely of Natural Foods and Does Not Contain Any Medicines. Lyfft Can Be Used As A Between-Meals Snack To Give Additional Energy When Needed. Ideal for Weight-Watchers. Contains Only 5 Calories Per Wafer. * * * Eat As Many As You Like As Often as You Like * * * Get A Lift The Natural Way, Each Wafer Contains Approximately 5 Calories."

ACCOMPANYING LABELING: Package inserts entitled "What is Lyfft?"

LIBELED: 7–2–63, Dist. Utah.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements, including the name of the article, "Lyfft," which were false and misleading in that they represented and suggested that the article was natural and unusually high in quick energy in an amount which was low in calories; that it was adequate and effective for weight control and appetite appeasement; to promote physical and mental energy; to feel and do better and get more enjoyment out of life; to increase the vigor of laborers and athletes; and, by the control of weight, to prevent heart diseases, hardening of the arteries, high blood pressure, and a general shortening of the life span.

DISPOSITION: 2–10–64. Consent—claimed by Lyfft Distributors, Inc., Salt Lake City, Utah, and released under bond for relabeling.

7987. Protein tablets. (F.D.C. No. 49467. S. No. 40–839 X.)

QUANTITY: 97 cases, each containing 4 cardboard sleeves, each sleeve covering 2 boxes containing packets of 4 tablets each, at Waldwick, N.J., in possession of General Packaging Service, Inc.

SHIPPED: 10–26–61 and 10–30–61, from Hempstead, N.Y.

LABEL IN PART: (Case) "Protein World Wide Nutri-Health, Inc. * * * Pittsburgh 20, Pa. Health Thru Natural Nutrition Code 2 Protein," (sleeve and box) "World Wide Nutri-Health, Inc. Health Thru Natural Nutrition Natural or Organic Protein plus Nutri-Zymes-P Dietary supplement Formulated for and Distributed by World Wide Nutri-Health, Inc., Pittsburgh 20, Pa. * * * Nutri-Health Protein Tablets are offered as a primary source of protein if at least 12 tablets are taken 3 times daily. * * * Nutri-Zymes-P is our specially developed combination of the following digestion aiding enzymes: Papain–30 mg., Prolase–3 mg., Pepsin–2 mg., and Mylase–1 mg. * * * Fruit Flavored."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and repacked and labeled by the dealer.

LIBELED: 10–17–63, Dist. N.J.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading statements, including the name of the article, "Protein plus Nutri-Zymes-P," which represented and suggested that the article was of significant value for special dietary supplementation and for therapeutic use by reason of the presence therein of natural protein and enzymes; and that the article was adequate and effective to promote sound health, cell life and development, and digestion.

DISPOSITION: 1–16–64. Default—destruction.

7988. Yeast. (F.D.C. No. 47985. S. Nos. 62–248/50 T.)

QUANTITY: 5½ 200-lb. drums, 1¼ 125-lb. drums, and 1½-lb. drums, at St. Johnsbury, Vt., in possession of Mrs. Mildred Hatch.

SHIPPED: Between 6–4–62 and 6–29–62, from Milwaukee, Wis., and St. Louis, Mo.

ACCOMPANYING LABELING: Leaflets entitled "Answers To Some Questions About Yeast" dated "April 15, 1962"; and repack labels.

RESULTS OF INVESTIGATION: In the normal course of the dealer's business operations the bulk material described above was repacked, on order, into consumer-size bags of various sizes, and labeled as "Yeast" or "Yeast Extract."

The leaflets were prepared by the dealer and were delivered personally to the purchaser or mailed to prospective customers for the purpose of promoting sales of the articles.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of anemia, tiredness, and constipation; to reduce and gain weight; to build up tissue and improve assimilation; promote health and nerve function; and that the articles were unusually nourishing in an amount which was low in calories.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–11–64. Consent—claimed by Mrs. Hatch and relabeled.

7989. Prom-Tac capsules. (F.D.C. No. 50339. S. No. 61–309 A.)

QUANTITY: 1 drum containing approximately 12,000 capsules at El Segundo, Calif.

SHIPPED: 3–24–64, from Brooklyn, N.Y., by Success Chemical Co., Inc.

LABEL IN PART: (Drum) "Prepared for Rabin-Winters Corp. * * * Product PROM-TAC CAPSULES * * * 10 capsules provide 5 days and 5 nights relief * * * from nasal congestion due to the common cold and hay fever One Cold Capsule gives up to 12 hours' relief. * * * reduces sneezing and itching of the eyes * * * Helps clear nasal passages * * * reduces running nose and watering of the eyes * * * Formula: Each capsule contains: Belladonna Alkaloids (Total) 0.16 mgm. Atropine Sulfate 0.024 mgm. Scopolamine Hydrobromide 0.014 mgm. Hyoscyamine Sulfate 0.122 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. * * * Caution * * * Success Chemical Co., Inc. Brooklyn 7, N.Y."

LIBELED: 7–8–64, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that a single *Prom-Tac capsule* containing the amounts of the ingredients declared in the label would provide 12 hours of continuous relief of excessive sneezing and nasal discharge, running nose, watering and itching of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 8–4–64. Default—destruction.

7990. Acton cold capsules. (F.D.C. No. 50406. S. No. 87–273 A.)

QUANTITY: 16,240 capsules at Philadelphia, Pa., in possession of Vitamin Specialties Co.

SHIPPED: 10–25–63, from Inwood, N.Y., by Barrows Chemical Co., Inc.

LABEL IN PART: (Drum) "Barrows Chemical Co., Inc. * * * Inwood, L.I. 96, N.Y. Preparation Vitamin Specialties Order Number Attac T.D. Capsules * * * Each Capsule Contains: Atropine Sulfate 0.024 mg. Scopolamine Hydrochloride 0.014 mg. Hyoscyamine Sulfate 0.122 mg. Phenylpropanolamine HC1 50 mg. Chlorpheniramine Maleate 1 mg. Pheniramine Maleate 12.5 mg. Provides continuous relief from nasal congestion due to the common cold & Hay Fever Dosage: One capsule in the morning and one capsule at bedtime"; (btl.) "Formula No. 280 Acton Timed Disintegration Capsules Supplies prompt and prolonged relief for approximately 12 hours from nasal congestion due to the common cold and hay fever * * * One capsule in the morning and one at night * * * Vitamin Specialties Co. * * * Distributors Each Capsule Supplies Belladonna Alkaloids 0.16 mgm. Atropine Sulfate 0.024 mgm. Scopolamine HBr. 0.014 mgm. Hyoscyamine Sulfate 0.122 mgm. Phenylpropanolamine HC1 50 mgm. Chlorpheniramine Maleate 1.0 mgm. Pheniramine Maleate 12.5 mgm. * * * Contents * * * drain the nasal passages * * * reduce sneezing and itching of the eyes * * * reduce running nose and watering of the eyes. Caution: Not to be used by."

RESULTS OF INVESTIGATION: The capsules were shipped in a bulk drum and were thereafter repacked by the dealer into 30-, 60-, 100-, and 250-capsule bottles labeled as described above, and subsequently the capsules were returned to the bulk drum.

LIBELED: 7–30–64, E. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article (bulk and repack) contained false and misleading representations that a single capsule of the article containing the amounts of the ingredients declared in the label would provide approximately 12 hours' continuous relief from nasal congestion due to the common cold and hay fever; that it would help drain the nasal passages, reduce sneezing and itching of the eyes, and reduce running nose and watering of the eyes.

DISPOSITION: 9–30–64. Default—destruction.

7991. Continuous Action Cold Caps. (F.D.C. No. 50322. S. No. 7–906 A.)

QUANTITY: 9 cases, each containing 18 boxes of 12 10-capsule pkgs. each, 3 boxes of 12 10-capsule pkgs. each, and 29 10-capsule pkgs. each, at Baltimore Md.

SHIPPED: 2–6–64 and 3–3–64, from Allegan, Mich., by L. Perrigo Co.

LABEL IN PART: (Pkg.) "Read's Continuous Action Cold Caps * * * Two capsules a day give 24-hour relief from nasal congestion due to common colds and hay fever * * * continuous relief for a twelve hour period * * * Each Capsule Contains: Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Scopolamine Hydrobromide 0.014 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Phenylpropanolamine Hydrochloride 50 Mgm. Chlorpheniramine Maleate 1 Mgm. Pheniramine Maleate 12.5 Mgm. Warning * * * Caution * * * Read Drug & Chemical Co., Baltimore, Maryland, Distributors."

LIBELED: 6–29–64, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that a single capsule would provide 12 hours of continuous relief of excessive sneezing and excessive nasal discharge, watering of the eyes and running nose, swelling of the nasal tissues caused by the common cold and hay fever, and help drain nasal passages.

DISPOSITION: 7–31–64. Default—delivered to the Food and Drug Administration.

7992. Wheat germ oil capsules. (F.D.C. No. 49771. S. No. 8–601 A.)

QUANTITY: 1 ctn. containing 13,500 capsules, 3 100-capsule btls., 10 250-capsule btls., and 1 1,000-capsule btl., at Baltimore, Md., in possession of Miller Products Co.

SHIPPED: 10–18–63, from Newark, N.J.

LABEL IN PART: (Btl.) "Vita-Boost Wheat Germ Oil * * * Each capsule contains 6 minims of Wheat Germ Oil * * * Distributed by Miller Products Co. * * * Baltimore 15, Md."

ACCOMPANYING LABELING: Additional repack labels.

RESULTS OF INVESTIGATION: The article had been shipped in bulk and had been bottled and labeled as above by the dealer.

LIBELED: 2–4–64, Dist. Md.

CHARGE: 502(a)—while held for sale, the labeling of the article and the name of the article, "Vita-Boost," contained false and misleading representations that the article was adequate and effective to boost vitality, increase endurance, and build strength and energy.

DISPOSITION: 3–18–64. Consent—claimed by Warren G. Miller, t/a Miller Products Co., Baltimore, Md., and relabeled.

7993. Formula M_7. (F.D.C. No. 45861. S. No. 64–798 R.)

QUANTITY: 71 3.8-oz. jars at San Francisco, Calif.

SHIPPED: Between 6–8–61 and 6–9–61, from New York, N.Y., by Shorell Laboratories, Inc.

LABEL IN PART: (Jar and ctn.) "Formula M_7 evolved by one of the world's foremost Plastic Surgeons * * * Shorell Laboratories, Inc., Distr. * * * N.Y.C. Miami."

ACCOMPANYING LABELING: Leaflets entitled "Formula M_7," and booklet entitled "IMPORTANT: To every woman over 35 Formula M_7."

RESULTS OF INVESTIGATION: Examination showed the article to be a cosmetic cream-type of product having a slight odor of oil and fats.

LIBELED: 7–7–61, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective medical treatment for wrinkles and sagging, aging skin in older women, and a substitute for plastic surgery; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active drug ingredient.

DISPOSITION: On or about 9–26–63, Shorell Laboratories, Inc., claimed the article. Thereafter, pursuant to stipulation, the case was removed to the District of New Jersey. On 6–1–62, the Government served written interrogatories on the claimant. On 8–27–62, answers to the interrogatories were filed. On 3–6–64, the claimant, while not admitting the allegations contained in the libel and with an intention to terminate the litigation, consented to a decree condemning the article. The decree provided for the relabeling under bond or the destruction of the single jar of the article actually seized.

7994. Coty 60 Second facial cream. (F.D.C. No. 49097. S. Nos. 47–402/3 X.)

QUANTITY: 2,639 individually ctnd. ½-oz. tubes and 1,220 individually ctnd. 2¼-oz. tubes, at Memphis, Tenn.

SHIPPED: Between 3–4–63 and 5–28–63, from New York, N.Y., by Coty, Inc.

LABEL IN PART: (Tube and ctn.) "Coty 60 Second Facial Directions For Use * * * Coty New York Paris London."

ACCOMPANYING LABELING: Carton insert reading in part "Coty 60 Second Facial About the Product A Revolutionary Discovery * * * Directions for Use."

RESULTS OF INVESTIGATION: Analysis indicated that the article was a white, perfumed, oil-in-water cream, containing aliphatic hydrocarbons, esters, a hydroxybenzoate, a polyoxyethylene compound, and propylene glycol.

LIBELED: 7–9–63, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for flabby, puffy skin; that it removed tired lines, lifted sagging facial contours, stimulated facial circulation, permitting the skin to get nutrients from the bloodstream for a look of health, and guarded against blemishes, blackheads, and enlarged pores; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: 3–31–64. Default—destruction.

7995. Virilon hair dressing and scalp cleanser. (F.D.C. No. 49757. S. No. 51–271 X.)

QUANTITY: 24 8-oz. btls. and 100 4-oz. btls. of *hair dressing*, and 24 8-oz. btls. of *scalp cleanser*, at Billings, Mont.

SHIPPED: 4–12–63, from Jackson, Mich., by Virilon Products, Inc.

LABEL IN PART: (Btl.) "Virilon* Physician's Formula For the Hair and Scalp Highly Penetrating *Trade Name: Physician's Formula, Patented. Virilon Inc. Contents: 20 mcg. Estrodiol per ounce of alcohol (70% isopropyl) Lecithon. Cholesterol, Iso-cholesterol, Lanosterol as esters * * * Patented by Robert Liefmann * * * Hormone 20-X"; and "Virilon* Scalp Cleanser *Trade Name: Physician's Formula, Patented Virilon Inc. * * * mfgd. for Virilon Inc. * * * Jackson, Mich."

ACCOMPANYING LABELING: Leaflets reading in part "Virilon, Inc. * * * Jackson, Michigan Mode of Application of Virilon Treatment * * * 3. Apply Virilon Follicle Cleanser * * * 6. Apply Hormone Formula Virilon 20X" and "Biographical note on Dr. Liefmann * * * All Virilon Products are unconditionally guaranteed, both as to effectiveness as well as the Quality"; and streamer-type leaflets reading in part "Now Available A Medical Approach to Healthier Hair and Scalp Virilon 20X Formula. Not a common hairdressing . . . not a patent medicine . . . not a gimmick baldness cure * * * Distributor Paris Beauty Supply * * * Billings, Montana."

LIBELED: 1–30–64, Dist. Mont.

CHARGE: Both articles, 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective as a hormone treatment of the hair, and that use of the articles was the most scientific way of developing healthier hair.

Hair dressing, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the steroids contained in the article penetrated the hair follicle and acted for approximately 60 hours thereby benefiting the hair, and that the article was a remarkable help for dandruff, itchy scalp, and thinning-hair condition; and 502(b)—the article failed to bear a label containing (1) the place of business of the manufacturer, and (2) an accurate statement of the quantity of contents.

DISPOSITION: 4–22–64. Default—destruction.

7996. Infra Massage device. (F.D.C. No. 44239. S. No. 97–996 P.)

QUANTITY: 199 individually ctnd. devices at Memphis, Tenn.

SHIPPED: Between 7–1–59 and 12–21–59, from Los Angeles, Calif., by Broadway Department Store, Inc.

LABEL IN PART: (Ctn.) "New Improved Model * * * Infra Massage International Biotical Corp., New York 23, N.Y."

ACCOMPANYING LABELING: Leaflet in carton entitled "Infra Massage"; and display card entitled "Arthritis and Rheumatic-like Pains."

RESULTS OF INVESTIGATION: Examination showed the article to be a portable hand unit consisting of a circular-shaped housing (hand grip attached) containing a vibrator motor, heat element, and regulator dial.

LIBELED: 2–17–60, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective

treatment for relieving arthritis, rheumatism, sinusitis, lumbago, cold discomforts, backache, bursitis, neuralgia, headaches, muscular strains and sprains, muscular aches and pains, arthritis and rheumatic-like pains, and tired feet.

DISPOSITION: The article was claimed by International Biotical Corp., New York, N.Y., and, on 5–4–60, the case was removed to the District of New Jersey. On 1–9–61, the claimant served written interrogatories on the Government, and, on 2–10–61, the Government served written interrogatories on the claimant. Answers to the written interrogatories were filed by the parties. On 2–15–61, upon consent of the claimant and the Government, the court ordered that the claimant and the Government be allowed to obtain 2 samples of the devices under seizure. On 1–29–63, the case came on for trial before the court. Upon conclusion of the trial on 2–1–63, the court reserved its decision. Thereafter, the parties filed post-trial memoranda. On 2–17–64, the court rendered the following opinion:

AUGELLI, *District Judge*: "This is an *in rem* seizure action arising under section 334 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 334. The libel of information in this case was originally filed in the United States District Court for the Western District of Tennessee. Pursuant to monition issued out of that court, the United States Marshall, at Memphis, Tennessee, seized a number of 'Infra Massage' devices which were individually packaged in cartons, together with the instruction leaflets contained in said cartons, and a counter display card. A claim to the seized devices was duly filed by the claimant, International Biotical Corp., and, upon application made by it to the court in Tennessee, the action was removed to this Court for trial.

"The libel alleges, in paragraph 3 thereof, that the seized devices were misbranded when introduced into and while in interstate commerce within the meaning of 21 U.S.C.A. § 352(a), in that the labeling pertaining to such devices, namely, the cartons, leaflets and display card, contain statements which represent and suggest that the device 'is an adequate and effective treatment for relieving arthritis; rheumatism; sinusitis; lumbago; cold discomforts; backache; bursitis; neuralgia; headaches; musclar strains and sprains; muscular aches and pains; arthritis and rheumatic-like pains; and tired feet'. It is further alleged that said statements are false and misleading since the device is not an adequate and effective treatment for such conditions and purposes. The libel concludes with the usual prayer for condemnation of the devices. The answer filed on behalf of claimant admits the identity of the seized property and its shipment in interstate commerce, but denies the charges of misbranding.

"Claimant concedes that the written, printed, or graphic matter appearing on the seized cartons, leaflets, and the counter display card all constitute 'labeling' within the meaning of the Federal Food, Drug, and Cosmetic Act. Thus, there remains to be determined only whether such labeling does in fact represent and suggest that the device 'is an adequate and effective treatment' for relieving the several conditions mentioned in paragraph 3 of the libel, and, if so, whether such alleged representations and suggestions are false or misleading. Having alleged that the device in suit is misbranded because the labeling used in connection therewith is false and misleading, the libelant has the burden of establishing this charge by a fair preponderance of the evidence. *United States* v. *60–28 Capsule Bottles, etc.*, 325 F. 2d 513 (3 Cir. 1963).

"An examination of the device shows it to be a small, 7 watt, electrically operated, portable, hand unit to which is attached a line cord with a plug at the end of the cord. The device is made to operate by inserting the plug into any 110–115 Volt 60 Cycle AC outlet. When in operation, the device will generate heat or produce vibration. A switch attached to the device gives the user a choice of low heat, high heat, heat and vibration, or vibration alone. The face pla[t]e of the device, circular in shape and measuring about 3¼ inches in diameter, transmits the heat, or the vibration, or both, to the point of application. The heat generated by the device is imparted to the point of application by infrared radiation and by conduction.

"Consideration will now be given to the alleged false and misleading statements contained in the labeling concerning the efficacy of the device. The label-

ing, as mentioned earlier in this opinion, consists of the counter display card, the cartons, and the leaflets.

"In red and black lettering, varying in size and prominence, the counter display card is designed to attract the attention of persons suffering from arthritic and rheumatic-like pains. The prospective purchaser is told that, from the infrared heat and massage properties of the device, he can expect fast muscular pain relief and quick temporary relief of minor aches and pains often associated with arthritis, rheumatism, sinusitis, lumbago, cold discomforts, backache, bursitis, neuralgia, tired feet, simple headaches, muscular strains and sprains, and muscular aches and pains due to overexertion or fatigue. The card also indicates recommendation by doctors, and mentions the 4-way action of the device, namely, heat plus massage, massage only, high heat, and low heat. The finishing touch is the picture of an attractive young lady in a bathing suit, shown using the device on the thigh of her leg.

"The carton, which is fitted into the counter display card to form part of the exhibit, graphically portrays, on some of its panels, the device contained therein. The message on one panel is that the device is intended for use for quick temporary relief of minor aches and pains often associated with the same conditions (which are repeated) as are mentioned on the counter display card. On other panels of the carton appear illustrations of the use of the device on different parts of the body, and statements that the device gives effective heat in 3 minutes, stimulates local circulation, helps relieve muscular tension, goes to work where it hurts, and gives blessed 'on the spot' relief.

"The leaflet, containing instructions for use of the device, repeats the same general message as the other pieces of labeling. Again there are illustrations showing use of the device on different parts of the body. The purchaser of the device again is told that the device is intended for use whenever heat or massage is indicated for temporary relief of minor aches and pains often associated with the conditions therein mentioned, which are repetitive of those enumerated on the counter display card and carton.

"Libelant contends that this labeling contains false and misleading statements, and that the device is, therefore, misbranded within the meaning of section 352(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §352(a). That section provides that a device shall be deemed misbranded if its labeling is false or misleading in any particular. Section 331 of the same Act prohibits the introduction into interstate commerce of any device that is misbranded, and section 321(n) thereof provides that:

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

"Libelant's proof in support of its charge of misbranding included the testimony of physicists who described the physical capabilities of the device, the testimony of doctors who made a medical evaluation thereof, and the testimony of a psychologist regarding the message conveyed by the labeling. Claimant's witnesses were a medical doctor who also made a medical evaluation of the device, and a psychologist who gave his opinion of the average consumer's reaction to the labeling. Before proceeding to outline the testimony given by these several witnesses, it may be noted that there was general agreement among the doctors that heat is an extremely old form of therapy. It is an analgesic agent, used to relieve or diminish pain. Libelant stipulated that heat is an adequate and effective treatment for the relief of aches and pains. More specifically, in answer to one of the claimant's interrogatories, libelant admitted that 'the device may be of some very minor benefit for localized use in the temporary relief of minor muscular aches and pains due to fatigue and over-exertion.'

"Dr. Earle K. Plyler and Dr. Robert C. Gore were the physicists called by libelant to testify as to the physical capabilities of the device.

"Dr. Plyler said there are several sources of infrared radiation, the most common being a heated object. He measured the temperature of the device in suit, and found that it reached a maximum of 52 degrees Centigrade (125.6 degrees Fahrenheit) at the center of the face plate after being turned on for 7½ minutes. At such time, the outer edge of the plate read 47 degrees Centigrade, and, after the device was placed on the arm and rubbed up and down, the temperature dropped to 34 degrees Centigrade. The greatest amount of infrared radiation emitted by the device, according to Dr. Plyler, occurred at a wave-len[g]th of approximately 9 microns, and he stated that at this wavelength the infrared radiation has very poor penetrability into the human skin, the extent thereof depending upon the thickness and condition of the skin and point of application. The witness also said that the infrared radiation emitted by the device would manifest itself to the user by a feeling of warmth below the surface of the skin, caused slightly by the infrared, but mostly by conduction of heat from the outer layers of skin. Dr. Plyler admitted he made no tests to determine the energy output of the device. Accepting the 7 watts figure appearing on the device as being indicative of the power put into it, the witness was nevertheless of the opinion that the infrared radiation emitted by the device was small compared to the wattage put in, estimating such emission to be something like 10 or 11 percent.

"Dr. Gore, the second physicist called by libelant, measured the infrared radiation emitted by the device by means of a spectrophotometer. This witness also found that the device reached its maximum emission of infrared radiation at approximately the 9 micron wave-length, that the infrared radiation emitted by the device penetrates the skin only to a depth of 1/50th of an inch, and that there would be complete absorption at this depth. Dr. Gore did not consider this to be an appreciable amount of penetration.

"Before considering the medical testimony regarding the efficacy of the device, it is well to stress at this point libelant's contention that infrared radiation, to be of value in relieving pain, should either penetrate deep into body tissue or heat the surface tissue sufficiently to cause the deeper tissues to be heated by conduction. Libelant says that the depth of penetration of the infrared radiation given off by the device (1/50th of an inch) is insignificant to relieve pain, and that its temperature (52 degrees Contigrade) does not generate sufficient energy to heat the deeper tissues by conduction.

"Libelant's medical evaluation of the device was presented through the testimony of Dr. Joseph B. Rogoff, Dr. Milton Lowenthal and Dr. Emory Stoner, all specialists in physical medicine.

"Dr. Rogoff tested the device for the Food and Drug Administration. He applied it to himself and to some of his patients, utilizing the instructions for use which accompanied the device. So far as he was concerned, the witness said, the device was not applied to relieve any painful condition, but merely to enable him to feel the amount of heat and vibration produced by it. The doctor did not measure the temperature of the device, but from the way it felt to him, he thought the temperature was not over 103 degrees Fahrenheit. The substance of this witness's direct testimony was that he did not consider the amount of heat and vibration generated by the device as adequate for the relief of pain, and that he did not observe any relief from pain in his use of the device. The witness also stated that he would not recommend the use of the device for the relief of pain of any of the conditions enumerated in the labeling, and that he knew of no doctor who would make any such recommendation. Additionally, Dr. Rogoff said that, to the best of his knowledge the view expressed by him was in conformity with the consensus of informed medical opinion.

"The testimony disclosed that the six patients tested by Dr. Rogoff with the device were each given only a single treatment, lasting from 5 to 10 minutes. Moreover, these patients were not suffering with minor aches and pains, but with conditions much more serious in nature. The doctor admitted that no form of heat therapy (except possibly "ultrasound" which is not involved in this case) would relieve such serious conditions by a single treatment lasting only from 5 to 10 minutes. The doctor acknowledged, however, that heat treatments would give temporary relief from these conditions, but said it was his practice to apply what he termed 'effective heat' to the pain area for at least 20 to 30 minutes, with more than one treatment daily if necessary. The witness frankly stated he did not expect his 6 tested patients

to respond to the single 5 or 10 minute applications he made of the device, and also admitted that if, according to his own standards, the device did emit sufficient heat, a single 5 or 10 minute application to the conditions he treated would not result in adequate relief.

"Aside from these tests, there was other testimony by Dr. Rogoff concerning heat therapy. In this connection the witness said that the temperature of skin is less than that of the body, the former running to a maximum of 94 or 95 degrees Fahrenheit, and the latter being 98.6 degrees Fahrenheit. The application to the skin of any object having a greater temperature than 95 degrees Fahrenheit would result in the transportation of conductive heat to the skin. Any form of heat, said the doctor, whether conductive or infrared, would be helpful in the treatment of traumatic and inflammatory conditions such as sprains, strains and bursitis, as well as pain symptoms of arthritis and neuralgia, provided the source is sufficiently hot and applied for at least 20 minutes. A temperature ranging from 110 to 112 degrees Fahrenheit was considered by the witness to be adequate, and even though such heat emanated from a device having a face plate of only 3½ inches in diameter. With respect to the device in suit, Dr. Rogoff said that, if it maintained a temperature of 110 degrees Fahrenheit, he would consider that it emitted effective heat. It is to be noted that libelant's witness, Dr. Plyler, testified that the device reached a maximum temperature of 52 degrees Centigrade (125.6 degrees Fahrenheit) at the center of the face plate, with a tapering off of such temperature at the edges of said plate. Dr. Rogoff did not disagree with a statement quoted from an article appearing in a medical publication that '[m]uch relief can be obtained from the simplest forms of heat treatment which may be carried out by the patients themselves in their own homes'.

"Dr. Milton Lowenthal, the next medical witness called by libelant, testified concerning his familiarity with the use of heat in relieving the painful conditions of arthritis, bursitis, myositis, lumbago, cold discomfort, backache, neuralgia, tired feet, simple headaches, muscular strains and sprains, and muscular aches and pains. Infrared heat, said the doctor, is one of the most convenient forms of applying heat to the affected parts, but to be effective in the conditions mentioned, the heat must be applied in sufficient volume over the painful area and for a sufficient period of time. This witness conducted clinical tests for the Food and Drug Administration on 10 patients over a period of at least 6 months. Each patient was subjected to 12 treatments, scheduled for 3 times a week, each treatment being of 20 minutes duration. The treatments were given by a registered physical therapist, in accordance with Dr. Lowenthal's instructions to turn on the device for 5 minutes before application to insure operation at its optimum condition, to expose the patients to each of the 4 settings of the device, and to continue to move it over the painful area for 20 minutes. The therapist was also instructed to make a record of the patients' reaction to the treatments and the effect thereof.

"The doctor stated that the tested patients were suffering from bursitis shoulder conditions, myositis, low back strain, aches and pains in the area of healed fractures, rheumatoid arthritis, and the like. Of the 10 patients treated, the records of only 7 were available to be produced in court. According to Dr. Lowenthal, only 2 of the patients reported they felt much better, the other 5 patients either experienced no relief, or relief that was so transitory, as to have no significant effect in terms of therapy. It was the doctor's opinion that the device had a record of effectiveness no different than what could be expected from the use of a placebo or sugar pill. He also noted that the device had no physiological effect on the skin, except that caused by the movement of the device over the affected area.

"Dr. Lowenthal further testified that his opinion regarding the efficacy of the device was based not only on the subjective responses of his patients and the absence of any physiological changes in the skin, but also on observations made concerning mobility of the painful joints, ability of the physical therapist to properly evaluate the subjective responses of the patients, and the need for more treatment. He also pointed to the fact that every time a patient with a chronic ache or pain is exposed to some new device, the tendency is for the patient to report relief. Based on the tests conducted on the 10 patients, Dr. Lowenthal concluded that the device was of no value in the 'management' of the conditions mentioned in claimant's labeling, and also said that the views expressed by him reflected the informed consensus of

medical opinion on the subject. An examination of the 7 charts comprising the report made by the physical therapist to Dr. Lowenthal reveals the following:

"Patient #1 suffered from an old fracture and arthritis of the right knee. The physical therapist reported that this patient obtained relief from the treatments in varying degrees, lasting from 1 to 2 hours to a maximum of 2 days; also, that such relief was temporary since the pain and discomfort always returned, but with lesser intensity than before treatment. This patient's subjective observation recorded at the conclusion of the treatments was that she felt 'much better'.

"Patient #2 had rheumatoid arthritis. The physical therapist reported that this patient obtained relief from the treatments in varying degrees, lasting from 1 to 2 hours to a whole day. Such relief, however, was temporary, in that the pain always returned, at times with the same intensity, once with greater intensity, and at other times with lesser intensity than before treatment. This patient's subjective observation at the conclusion of the treatments was that he felt a 'little better'.

"Patient #3 was suffering with a right shoulder syndrome. As to this patient, the physical therapist reported that some relief was obtained from the treatments in varying degrees, lasting 3 to 4 hours to a maximum of from 2 to 3 days; also, that such relief was temporary because the pain always returned, but usually with a lesser degree of intensity. This patient's subjective observation at the conclusion of the treatments was that she felt 'much better from the heat'.

"Patient #4 suffered from a pain in her left shoulder. In this case the physical therapist reported that the patient exhibited improvement in range of motion and use of arm, as well as some relief from pain throughout the treatments. The relief lasted for periods ranging from 3 to 4 hours following treatment to 8 to 9 days, with ouly a slight return of pain, but with increased function of the arm. This patient's subjective observation at the conclusion of the treatments was that she had 'less pain than before treatment'.

"Patient #5 had a low back sprain. The physical therapist reported that this patient obtained relief from the treatments in varying degrees, such relief lasting from 3 to 4 hours immediately following treatment and extending to a maximum of 1 or 2 days after treatment. It was further reported that at the end of the series of treatments the relief appeared to be permanent, the patient stating there was no return of pain; also, that during the course of the treatments, palpable spasm became less and disappeared, as did any pain incurred on palpitation. The last subjective observation noted for this patient following treatment was that he felt 'very good'.

"Patient #6 suffered from myositis of the left scapula and lumbosacral areas. With respect to this patient, the physical therapist reported that some relief was obtained from the treatments, but that such relief was temporary, lasting from 3 to 7 hours following treatment. The therapist also reported that the pain generally returned, and that at times no relief was obtained. In some instances there was less pain and spasm on palpitation, and at other times pain and spasm remained with the same intensity. It appeared to the therapist that the scapular pain was somewhat lessened temporarily due to treatment, but that the sacroiliac pain did not respond and that slight, if any, improvement was noted in this area. The last subjective observation of this patient following treatment was that she felt the same as before treatment with 'no change in intensity of pain'.

"The last patient, #7, for whom a chart was available, suffered from a fracture of the right patella. The physical therapist reported in this case that the patient obtained temporary relief from the treatments, lasting from 1 hour to a maximum of 1 or 2 days. Throughout the course of the treatments, the therapist noted no change in the appearance of the knee, except that occasionally there was less pain on palpitation and a slight decrease of edema. At the conclusion of the treatments, this patient's subjective observation was that she felt 'a little better'.

"The last medical witness called by libelant was Dr. Emory K. Stoner. This witness explained that any body or object that is hotter than another gives off infrared radiation. The doctor stated that he considered the device in suit to be capable of producing heat, but that he did not evaluate it as being medically adequate because, in his opinion, it did not generate sufficient heat. The witness also testified that he would not use the device in his practice, that

in his opinion the device would not relieve the aches and pains of the conditions enumerated in claimant's labeling, that he knew of no doctor who would use it for such conditions, and that the views expressed by him concerning the efficacy of the device reflected the consensus of opinion in the field. In sum, it was Dr. Stoner's opinion that infrared heat, as used in medicine, should either penetrate into underlying tissues, or provide sufficient heat on the surface so that it will reach the deeper tissues by conduction.

"There was other testimony by Dr. Stoner, some of it based on an article written by him in a medical publication, which disclosed that authorities differ regarding the depth to which infrared radiation of different wave-lengths can penetrate the body. Penetrability would depend upon the condition and thickness of the skin. The thickness of human skin, said the doctor, varies, but it generally averages 1 to 2 millimeters. The witness stated that at wave-lengths ranging from 1.5 to 15 microns, penetrability of the infrared rays would be from .05 of a millimeter to 1 millimeter. Below a wave-length of 1.5 microns, the penetrability could be as much as 2 millimeters. The doctor admitted that penetration of the human skin to a depth of .05 of a millimeter to 1 millimeter, obtainable at a wave-length between 1.5 to 15 microns, was medically recognizable penetration to the extent that it produces a physiologic action upon the skin in the form of thermal and nerve stimuli. The device in suit, having a peak emission of infrared radiation at a wave-length of 9 microns, would thus be capable of effecting skin penetration to a depth ranging from 0.5 of a millimeter to 1 millimeter. The doctor agreed that if one had an infrared producing device that penetrated the skin to the extent of ½ millimeter (1/50th of an inch), the physiologic action upon the skin or tissue would be somewhat the same as the physiologic action resulting from a penetration of 1 millimeter (1/25th of an inch). In sum, said Dr. Stoner, heat is heat, and so far as the body is concerned, beneficial results are obtained thereby, if it is adequate in amount.

"The only medical witness called by claimant was Dr. William H. Kammerer, a specialist in internal medicine, with a special interest in rheumatic disease and arthritis. This witness's familiarity with the device went back to when it was first being developed in 1954, 1955 or 1956. He first tried the device on himself, and then gave it to a number of his patients (between 20 and 30) to use. The application of the device to himself, said the doctor, was not for the purpose of relieving pain, but to test it for warmth and to determine if it generated heat to an extent that might be harmful. In this connection, the doctor applied the device to the anterior surface of his thigh, moving it up and down slowly, and noted that the feeling of warmth remained during the entire operation. The witness recalled testing the device at the different temperature settings, and stated that his opinion regarding the efficacy of the device applied to them all. As to the element of vibration, it was stated that vibration alone might be of value in certain cases, but that greater benefit would result by the use of heat alone, or heat with vibration.

"Dr. Kammerer admitted that in the intervening years since he tested the device, he did not prescribe it for use by any of his patients, nor did he use it in his own practice. However, said the doctor, this did not alter his opinion regarding the effectiveness of the device in relieving aches and pains. He added that it was his practice, when prescribing a modality or drug, to use a generic rather than a brand name, unless the desired modality or drug is not available by its generic name. An apparent deviation from this practice might be said to have occurred when the doctor, in response to inquiries made by a number of his patients who showed him advertisements of the device, advised them he had no objection to its use. In sum, Dr. Kammerer said that, in his opinion, the device was effective in relieving the minor aches and pains of muscular stiffness, and of arthritic and rheumatic conditions. More specifically, and eliminating the conditions of sinusitis, tired feet, and simple headaches because, as he said, they were out of his field, the doctor stated that the device, in his opinion, produced an analgesic effect, and was efficacious in affording temporary relief of the minor aches and pains associated with the other conditions mentioned in claimant's labeling. And this opinion, said Dr. Kammerer, was based on the use of the device, and what had been reported to him by the users thereof.

"There is no need to do more than dwell briefly on the testimony of the two psychologists who were permitted to testify concerning the message conveyed

by claimant's labeling to prospective purchasers of the device. Both experts saw the same displays, both read the same language, and, as is not unusual with experts, each came to a contrary conclusion regarding the meaning of the language employed and its impact upon the average consumer.

"Dr. Godfrey M. Hochbaum, holding degrees in psychology and sociology, who testified for libelant, was of the opinion that most people would be led by claimant's labeling to believe that the device will provide relief over a large area from all pains of arthritis, rheumatism and other listed conditions, and that these people would overlook the qualifying words 'minor' and 'temporary'. In other words, according to this witness, the person suffering with pain would consider the device not only adequate for temporary relief of minor aches and pains, but also for relieving severe pain and deep pain.

"Dr. Harvey Queen, also a qualified psychologist, who testified for claimant, was of the opinion that claimant's labeling, taken as a whole, would convey to the average consumer nothing more than that the device provides temporary relief from minor aches and pains associated with the listed conditions. In support of his opinion as to how the average consumer would understand and react to the labeling, the witness pointed to the many popular analgesic products on the market, such as Aspirin, Bufferin and Anacin, which employ language similar to that used by claimant. In this connection, it may be noted that libelant conceded that there were a number of pain relieving products on the market which employ language similar to that appearing in the labeling in suit, and specifically the statement, 'quick temporary relief of minor aches and pains'.

"In the opinion of this Court, the labeling involved in this case 'contained nothing of a scientific or technical nature which required explanation or the assistance of an expert for an understanding of its meaning or contents'. *Vibra Brush Corp.* v. *Schaffer*, 152 F. Supp. 461, 468 (S.D. N.Y. 1957).

"Based upon a consideration of all of the evidence in the case, the Court makes the following findings of fact:

"1. The device under seizure and all labeling connected therewith were shipped in interstate commerce.

"2. Said labeling, consisting of the counter display card, cartons, and instruction leaflets, are intended to explain the purposes and uses of the device, and promote its sale.

"3. Said labeling does not, as alleged in paragraph 3 of the libel, contain statements which represent and suggest that the device 'is an adequate and effective treatment' for relieving the conditions enumerated in said paragraph 3.

"4. Said labeling represents and suggests only that the device affords quick temporary relief of minor aches and pains 'often associated with' the conditions enumerated in paragraph 3 of the libel.

"5. Heat is an extremely old form of therapy. It is an analgesic agent, and is medically recognized as an adequate and effective treatment for the relief of aches and pains.

"6. The heat generated by the device is imparted to the point of application by infrared radiation and by conduction.

"7. A temperature of 110 to 112 degrees Fahrenheit is adequate for the temporary relief of pain. The device in suit is capable of producing heat up to 125.6 degrees Fahrenheit.

"8. Penetration of the human skin to a depth ranging from .05 of a millimeter to 1 millimeter, obtainable at a wave-length of from 1.5 to 15 microns, is medically recognizable penetration to the extent that it produces a physiological action upon the skin in the form of thermal and nerve stimuli. The device in suit, having a peak emission of infrared radiation at a wave-length of 9 microns, is capable of producing such action.

"9. The record as a whole, including tests performed by libelant's witnesses, fails to establish that the device does not emit sufficient heat to afford temporary relief of minor aches and pains 'often associated with' the conditions enumerated in paragraph 3 of the libel.

"Based upon the foregoing findings of fact and other facts stated in this opinion, the Court concludes, as a matter of law, that the libelant has failed to meet its burden of establishing by a fair preponderance of the evidence that the representations and suggestions made in the labeling are false or misleading, and that the device is misbranded within the meaning of section 352(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S. C.A. § 352(a) as alleged in

paragraph 3 of the libel. Accordingly, claimant is entitled to a dismissal of the libel and to a return of the seized devices.

"This disposition of the case makes it unnecessary for the Court to consider the effect of the order obtained by claimant in its favor in the proceeding instituted against it by the Post Office Department.

"Submit order."

7997. Negative ion generator devices. (F.D.C. No. 48969. S. No. 85–497 V.)

QUANTITY: 834 devices at Seattle, Wash.

SHIPPED: 3–21–63, from Los Angeles, Calif., by Roberts Electronics, Inc.

LABEL IN PART: (Front of Model IG–200 device) "Robert's Negative Ion Generator"; (front of Model IG–1 device) "Negative Ion Generator"; (back of devices) "A Product of Roberts Electronics, Inc. Los Angeles, California."

ACCOMPANYING LABELING: Leaflets entitled "A Reader's Digest Reprint Ions Can Do Strange Things To You" and brochure entitled "The Roberts Negative Ion Generator."

RESULTS OF INVESTIGATION: Examination indicated the articles to consist of brown-colored metal cabinets with gold-colored mesh fronts, black filter pads, and electrical connections. The Model IG–200 contained 4 "Odorout" bulbs and 2 4-blade fans with electric motors; and the Model IG–1 contained 2 "Odorout" bulbs and 1 4-blade fan with electric motor.

LIBELED: 5–21–63, W. Dist. Wash.; libel amended on or about 6–7–63.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the articles were adequate and effective for treating respiratory complaints; insomnia; aching joints; asthma; hay fever; reducing redness and the need for skin grafting in severe burns; increasing mucous flow, thereby freeing air passages of dust and pollen by speeding up ciliary beat in bronchial tubes and trachea; acceleration of absorption and utilization of oxygen in cells and tissues; stimulation of the reticuloendothelial system, thereby increasing resistance to disease; elevating moods; tranquilizing persons in severe pain; elimination or radical reduction of deep postoperative pain; and reducing crankiness in children, and the crime and suicide rate.

DISPOSITION: 9–18–63. Default—delivered to a Government institution for use of the electronic parts.

7998. Slim Swivel device. (F.D.C. No. 49789. S. No. 103–145 A.)

QUANTITY: 38 individually ctnd. devices at Portland, Oreg.

SHIPPED: 12–2–63, from Louisville, Ky., by National Products, Inc.

LABEL IN PART: (Ctn.) "Slim Swivel * * * National Products, Inc. Louisville 4, Ky. Hip Hip Away."

ACCOMPANYING LABELING: Leaflets entitled "The Slim Swivel by National" and "50 Mile hikes are not for everyone but simple exercise is essential The Slim Swivel by National."

RESULTS OF INVESTIGATION: The article consisted of a small platform for self-exercise, about 1 foot square, which was attached to a similar base with a swivel-type connection.

LIBELED: 3–4–64, Dist. Oreg.

CHARGE: 502(a)—when shipped, the labeling of the article, including its name, contained false and misleading representations that the article was adequate

and effective for slimming down hips, for reducing fatty tissue collected around the waist, improving posture and health, taking off that middle roll, keeping the spine supple, free, and normal, toning up back and stomach muscles, straightening up shoulders and for other medical purposes.

DISPOSITION: 4–13–64. Default—released to the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

7999. Edds Poultry Tonic and Stock Conditioner. (Inj. No. 482.)

COMPLAINT FOR INJUNCTION FILED: 3–4–64, N. Dist. Ohio, against Floyd H. Edds, Defiance, Ohio.

NATURE OF BUSINESS: The defendant was engaged in the business of manufacturing, packaging, labeling, selling, and distributing in interstate commerce, articles of drug, namely, medicated stock feed designated as *"Edds Poultry Tonic"* and *"Edds Stock Conditioner."*

LABEL IN PART: (Pkg.) "Edds Poultry Tonic A Tonic For All Age Fowl Directions: * * * Statement of Ingredients: Sulphur-White Midlings—Linseed Meal—Bi-Carbonate Soda—Jamica Ginger—Blood Root—Capsicum Crude Protein 4% Crude Fat 1% Crude Fiber 5% Contents 50 lbs. net Prepared and Sold by Floyd Edds, * * * Defiance, Ohio" and "Edds Stock Conditioner A Tonic For All Poultry, Hogs and Cattle Directions: * * * Statement of Ingredients Sulphur—White Middlings—Linseed Meal—Bi-Carbonate Soda Jamaica Ginger—Blood Root—Capsicum Crude Protein 4% Crude Fat 1% Crude Fiber 5% Contents * * * lbs. net Prepared and Sold by Floyd Edds, * * * Defiance, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "Edds Stock Conditioner * * * Prepared and Sold by Floyd Edds, Rt. 8, Defiance, Ohio" and "Edd's Poultry and Hog Tonic for Chickens, Turkeys and Hogs Prepared and Sold by Floyd Edds Route 8 Defiance, Ohio."

CHARGE: 502(a)—when shipped, the labeling of the articles, including the names *"Poultry Tonic"* and *"Stock Conditioner,"* contained false and misleading representations that the articles were adequate and effective as an appetizer, a preventive of colds, worms, blue comb, blackhead and coccidiosis in poultry and as a very good body builder; that the articles kept flocks healthy and in good egg production; and that the drugs were good for scours, worms, and as an appetizer and conditioner for hogs.

The complaint alleged further that if the defendant were merely restrained from introducing the drugs into interstate commerce because of false and misleading labeling, the defendant would not discontinue interstate distribution of the drugs but would continue to ship them in interstate commerce without specifying in their labeling the purposes and conditions for which they were intended. In these circumstances, the drugs would be misbranded under 502(f)(1), in that their labeling would not bear adequate directions for use because of the omission from their labeling of the purposes and conditions for which the drugs were to be used.

DISPOSITION: 4–28–64. The defendant having consented, the court entered a decree of permanent injunction against the defendant enjoining him from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the articles

*See also Nos. 7947, 7979–7981.

of drug designated as "*Edds Poultry Tonic*" and "*Edds Stock Conditioner*" by those names or by any other names, or any similar articles of drug (1) which were accompanied by the leaflets entitled "Edds Stock Conditioner * * * Prepared and Sold by Floyd Edds, Rt. 8, Defiance, Ohio" and "Edds Poultry & Hog Tonic for Chickens, Turkeys and Hogs. Prepared and Sold by Floyd Edds Route 8 Defiance, Ohio," or by any other written, printed, or graphic matter substantially to the same effect; (2) which bore or were accompanied by any written, printed, or graphic matter, which stated, suggested, represented or implied that the articles were adequate and effective as an appetizer, a preventive for colds, worms, blue comb and coccidiosis in poultry, and as a very good body builder; that the drugs kept flocks healthy and in good egg production; and that they were good for scours, worms, and as an appetizer and conditioner for hogs, or which was otherwise false and misleading; and (3) which did not bear or were not accompanied by written, printed, or graphic matter which contained adequate directions for use including the conditions and purposes for which the drugs were to be used or for which the drugs were offered.

DRUG ACTIONABLE BECAUSE OF INCONSPICUOUS LABELING INFORMATION

8000. Revlon Silicare lotion. (F.D.C. No. 48826. S. No. 66–009 V.)

QUANTITY: 68 btls. of 6 fl. ozs. each, at Brooklyn, N.Y.

SHIPPED: 1–28–63 and 3–18–63, from Edison, N.J., by Revlon, Inc.

LABEL IN PART: (Sticker label on btl. front) "Revlon Medicated Silicare Protective Lotion For Hands & Body NEW! IMPROVED! Actually Promotes Healing * * * Medically Tested and Proven Revlon Pharmacal Division"; (embossed label on btl. front) "Revlon, Inc., N.Y. Made in U.S.A. Net Contents 6 Fl. Ozs."; and (printed label on btl. back) "Medicated Silicare * * * Directions: * * * Important: * * * Caution: * * * Contains."

LIBELED: 4–3–63, E. Dist. N.Y.

CHARGE: 502(c)—when shipped, the information required to appear on the label under 502(b), namely, (1) the name and address of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

DISPOSITION: 6–7–63. Default—destruction.

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[1] (7967, 7999) Injunction issued.

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[1](7967, 7999) Injunction issued.

[2](7984) Seizure contested. Motions for summary judgment; contains opinions of the court.

[3](7993) Seizure contested.

[4](7968) Contempt of injunction. Prosecution contested. Contains judgment of the court.

[5](7996) Seizure contested. Contains opinion of the court.

[6](7955) Prosecution contested. Motion for discovery and inspection served. Contains opinion of the appellate court.

[7](7983) Seizure contested. Injunction issued; contains findings of fact and conclusions of law, and an opinion of the court.

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[1] (7967, 7999) Injunction issued.

[2] (7984) Seizure contested. Motions for summary judgment; contains opinions of the court.

[4] (7968) Contempt of injunction. Prosecution contested. Contains judgment of the court.

[7] (7983) Seizure contested. Injunction issued; contains findings of fact and conclusions of law, and an opinion of the court.

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[1](7967, 7999) Injunction issued.
[5](7996) Seizure contested. Contains opinion of the court.
[6](7955) Prosecution contested. Motion for discovery and inspection served. Contains opinion of the appellate court.

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[3](7993) Seizure contested.

[4](7968) Contempt of injunction. Prosecution contested. Contains judgment of the court.

[6](7955) Prosecution contested. Motion for discovery and inspection served. Contains opinion of the appellate court.

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Welton Laboratories, Inc.:	
safflower oil capsules and vitamin and mineral formula capsules	7954
World Wide Nutri-Health, Inc.:	
protein tablets	7987

U.S. GOVERNMENT PRINTING OFFICE:1965

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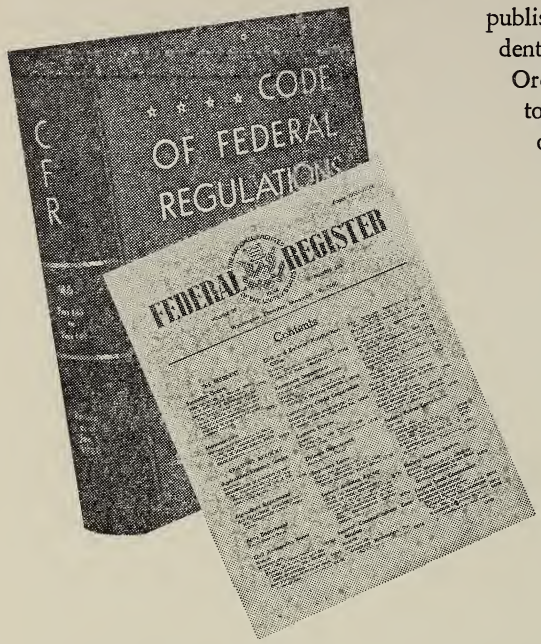

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D.D.N.J., F.D.C. 8001–8040 Issued June 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8001–8040

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default, or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *June 28, 1965.*

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*For omission of, or unsatisfactory, ingredients statements, see No. 8008; an imitation of, and sale under name of, another drug, Nos. 8031, 8032; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 8023; cosmetic actionable under the drug provisions of the Act, No. 8035.

774–881—65——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8001–8040

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or some other antibiotic drug, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

8001. Delayed disintegration tablets. (F.D.C. No. 49334. S. Nos. 25–522/3 X.)

QUANTITY: 1 11,978-tablet drum and 1 9,000-tablet drum, at Battle Creek, Mich.

SHIPPED: 8–23–62 and 11–9–62, from St. Louis, Mo., by Private Formulae, Inc.

LABEL IN PART: (11,978-tablet drum) "Rx #1521 * * * Compressed Tablets Delayed Disintegration Each tablet contains: d-Amphetamine Sulfate 10.5 mg. dl-Amphetamine Sulfate 10.5 mg. Caution * * * Dosage * * * Caution * * * Mfd. for: Paul Raisig * * * Battle Creek, Michigan * * * Manufactured by: Private Formulae Inc. * * * St. Louis 15, Mo."; and (9,000-tablet drum) "RX #1494 * * * Compressed Tablets Delayed Disintegration * * * Each Tablet Contains D-Amphetamine Sulfate 30 mg. Amobarbital -v- ½ gr. (May be Habit Forming) Caution * * * Warning * * * MFG. For: Paul Raisig * * * Battle Creek, Mich. * * * Manufactured by Private Formulae, Inc. * * * St. Louis 15, Mo."

LIBELED: On or about 9–19–63, W. Dist. Mich.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drugs.

DISPOSITION: 11–12–63. Default—destruction.

8002. Pentafin-80 capsules. (F.D.C. No. 48338. S. No. 24–413 V.)

QUANTITY: Approximately 8,200 capsules, in 100- and 500-capsule btls., at Detroit, Mich.

SHIPPED: 9–18–62, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl.) "Pentafin-80 Tutag Granucaps Pentaerythritol Tetranitrate 80 Mgm. Each capsule contains - - - Caution - - - S. J. Tutag & Co. Detroit 34, Michigan."

ACCOMPANYING LABELING: Brochure, attached to bottle, reading in part "Coronary Vasodilator in Sustained Release Form."

RESULTS OF INVESTIGATION: The article had been shipped in bulk from St. Louis, and repacked and labeled as above at Detroit, Mich.

LIBELED: On or about 10–26–62, E. Dist. Mich.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 12–13–62. Default—destruction.

8003. Feverill. (F.D.C. No. 49424. S. Nos. 54–915/16 X, 74–802 X.)

QUANTITY: 21 individually ctnd. gal. btls.; 4 ctns. of 48 1-oz. btls. each; 69 ctns. of 12 1-pt. btls. each; and 1 ctn. of 11 1-pt. btls., at St. Louis, Mo., in possession of E. W. Heun Co.

SHIPPED: 9–13–63, from Louisville, Ky. This was a return shipment.

LABEL IN PART: (Btl.) "Feverill Each CC (One Teaspoonful) Contains Methampyrone Sodium 500 Mg. Chlorpheniramine Maleate 0.5 Mg."

LIBELED: 10–18–63, E. Dist. Mo.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 12–20–63. Default—destruction.

8004. Vasopred ophthalmic solution. (F.D.C. No. 49408. S. No. 31–307 X.)

QUANTITY: 154 ctns. of 12 vials each, at Los Angeles, Calif.

SHIPPED: Between 8–28–63 and 9–19–63, from New Brunswick, N.J., by Carroll Dunham Smith Pharmacal Co.

LABEL IN PART: (Vial) "5 cc New Formula Vasopred Ophthalmic Solution * * * Smith, Miller & Patch, Inc. New York, N.Y."

LIBELED: 10–9–63, S. Dist. Calif.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 11–6–63. Default—destruction.

DRUG FOR VETERINARY USE

8005. Cardiobee 15 injection. (F.D.C. No. 49117. S. No. 40–304 X.)

QUANTITY: 10 10-cc. vials at Puerta de Tierra, P.R.

SHIPPED: 6–7–63, from Hialeah, Fla., by Zirin Laboratories International, Inc.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Sterile Vial Cardiobee 15 Injection each 10 cc. contains: 100 mg. of Na-Glucono-di (N-diisopropyl-

amino) Acetate * * * For veterinary use only Dist. by Zirin Enterprises Hialeah, Florida."

LIBELED: 7–23–63, Dist. P.R.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 10–11–63. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

8006. Antibiotic discs. (F.D.C. No. 50324. S. Nos. 97–917 A, 97–920 A.)

QUANTITY: 14 boxes of 50 No. GP–2 units each, and 13 boxes of 50 No. GN–2 units each, at Menlo Park, Calif.

SHIPPED: 4–8–64, from Omaha, Nebr., by National Bio-Test, Inc.

LABEL IN PART: (Box) "Desi-Disc Ring No. GP–2 For use in laboratory diagnosis only Manufactured by National Bio-Test, Inc., Omaha, Nebr. E+—Erythromycin 15 mcgs. * * * Distributed by Scientific Products Division American Hospital Supply Corporation * * * Evanston, Illinois," and "Desi-Disc Ring No. GN–2 * * * Manufactured by National Bio-Test, Inc., Omaha, Nebr. T+—Terramycin 30 mcgs. * * * Distributed by Scientific Products Division American Hospital Supply Corporation * * * Evanston, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that several of the antibiotics in each lot contained less than the declared potency.

LIBELED: 7–1–64, N. Dist. Calif.

CHARGE: 502(1)—when shipped, the articles purported to be and were represented as drugs composed wholly or in part of certifiable antibiotics, and they were not from batches with respect to which certificates or releases were in effect.

DISPOSITION: 8–18–64. Default—destruction.

DRUGS FOR VETERINARY USE

8007. CO-OP Nicarbazin Mixture. (F.D.C. No. 49650. S. No. 32–029 X.)

QUANTITY: 85 50-lb. sacks at Phoenix, Ariz., in possession of Southwest Co-Operative Wholesale.

SHIPPED: The article was manufactured from drug ingredients which were shipped on 5–31–63 and 6–18–63, from Azusa, Calif., and Los Angeles, Calif.

LABEL IN PART: (Tag) "CO-OP Nicarbazin Mixture Active Drug Ingredient: Nicarbazin (4, 4′ Dinitrocarbanilide 2 Hydroxy-4, 6′ dimethylpyrimidine)—0.125% * * * Ingredients * * * Chlortetracycline (Aureomycin) * * * Manufactured by Southwest Co-Operative Wholesale * * * Phoenix, Arizona * * * Poultry Feeding Program * * * Broilers and Fryers * * * 8 Weeks to Market Age. Co-Op Broiler Nicarbazin Mixture Crumbles or Pellets."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately .014 percent nicarbazin.

LIBELED: 12–24–63, Dist. Ariz.

CHARGE: 502(a)—while held for sale, the label statement "Nicarbazin 0.125%" was false and misleading; 502(f)(1)—the label failed to bear adequate directions for use, since it directed feeding of the article to broiler and fryer chickens at market age whereas the article, because of its nicarbazin content, may not safely be fed within 4 days prior to slaughter of the animal for food purposes; 502(f)(2)—the label failed to bear a warning statement that the article may not be fed within 4 days prior to slaughter of the animal for food purposes; and 502(l)—the article was represented as a drug composed in part of chlortetracycline and it was not from a batch with respect to which a certificate of release had been issued pursuant to law, and it was not exempt from certification.

DISPOSITION: 2–6–64. Default—destruction.

8008. Formula 707 medicated feed. (F.D.C. No. 48832. S. No. 13–791 V.)

QUANTITY: 1,617 lbs. in 10-, 25-, and 50-lb. drums, at Oshkosh, Wis.

SHIPPED: 11–16–62, from La Salle, Colo., by John Ewing Co.

LABEL IN PART: (Drum) "Performance and Show Conditioner Formula 707 * * * Selected Concentrated Dehydrated Green Forages Fortified With Additional Vitamins and Supplements For Improved Condition and Stamina For Race Horses Show Horses Cutting Horses Trail and Using Horses * * * Feeding Instructions * * * Ingredients * * * Manufactured by John Ewing Company, La Salle, Colorado."

ACCOMPANYING LABELING: Pamphlets entitled "How To Make Money With Formula 707 * * * a product of the John Ewing Company."

RESULTS OF INVESTIGATION: Analysis showed that the article contained chlortetracycline, a certifiable antibiotic, which was not listed in the label statement of ingredients.

LIBELED: 4–2–63, E. Dist. Wis.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for treatment of sickness and recovery from infection; and that the article was a complete health conditioner to maintain top condition and stamina, and peak muscular coordination of horses; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(l)—the article was composed in part of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 5–15–64. Consent—claimed by John Ewing Co., and relabeled.

8009. Medicated feed. (F.D.C. No. 50282. S. No. 87–502 A.)

QUANTITY: 131 100-lb. bags at Valley View, Pa.

SHIPPED: 4–9–64, from Buffalo, N.Y., by Eastern States Farmers' Exchange, Inc.

LABEL IN PART: (Tag on bag) "Eastern States Dienestrol Diacetate Mixture * * * to aid in Prevention of Cecal and Intestinal Coccidiosis in Chicken Flocks Active Drug Ingredients: Dienestrol Diacetate 0.0023% Sulfaquinoxaline 0.0125% Incorporated in Eastern States Roaster Finisher * * * Ingredient Formula * * * Bacitracin * * * Penicillin * * * Manufactured by Eastern States Farmers' Exchange, Inc. * * * Buffalo, N.Y."

LIBELED: 6–12–64, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Sulfaquinoxaline 0.0125%" was false and misleading as applied to a product containing less than the declared amount of this ingredient; 502(a)—the tag label contained false and misleading representations that the article was adequate and effective as an aid in the prevention of cecal and intestinal coccidiosis in chicken flocks; and 502(l)—the article was represented as containing bacitracin and penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to section 507, and it was not exempt from such requirement since it failed to conform to the exemption requirements of regulations by reason of the absence of sulfaquinoxaline in the article.

DISPOSITION: 7–29–64. Default—destruction.

8010. Medicated hog feed. (F.D.C. No. 50309. S. No. 34–420 A.)

QUANTITY: 30 100-lb. bags at Hebron, Ohio.

SHIPPED: 3–13–64, from Lawrenceburg, Ind., by The Quaker Oats Co.

LABEL IN PART: (Bag) "Full-O-Pep Hog Feed * * * Made By The Quaker Oats Company General Offices Chicago, U.S.A. * * * hog feed"; (tag) "Ful-O-Pep Gro-Pork 45 Supplement (Kl) L Medicated To stimulate growth and increase feed efficiency of swine when mixed with 4 to 7 parts grain * * * Active Drug Ingredient Arsanilic Acid 0.05% Streptomycin (from Streptomycin Sulphate) . . . * * * Gm/Ton Penicillin (from Procaine Penicillin) . . . * * * Gm/Ton * * * Made by The Quaker Oats Company, Chicago, Illinois * * * Directions For Use."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 60 percent in excess of the declared amount of arsanilic acid.

LIBELED: 6–24–64, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement (tag) "Arsanilic Acid 0.05%" was false and misleading as applied to a product containing in excess of the declared amount of this ingredient; and 502(l)—the article was represented as a drug composed in part of a kind of penicillin and streptomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirement since the article, when mixed as directed with four parts of grain, provided a level of the drug, arsanilic acid, which was in excess of the maximum amount provided for by regulations.

DISPOSITION: 7–30–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

8011. Amphetamine capsules and tablets. (F.D.C. No. 49289. S. Nos. 2–321/31 X, 2–334/7 X.)

QUANTITY: 32,900 *amphetamine tablets* and 16,500 *amphetamine capsules*, at Darlington, S.C., in possession of Leon T. Rousey; and 3,000 *amphetamine tablets* and 1,000 *amphetamine capsules*, at Society Hill, S.C., in possession of William Andrew Jacobs, t/a Johnnie's Truck Stop.

SHIPPED: On unknown dates, from outside the State of South Carolina.

*See also No. 8007.

LIBELED: 8–27–63, E. Dist. S.C.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage or distribution of prescription drugs, and the articles were not to be dispensed as required by regulations.

DISPOSITION: 10–3–63. Default—destruction.

8012. Amphetamine sulfate tablets and Nembutal Sodium capsules. (F.D.C. No. 49242. S. No. 15–671 X.)

QUANTITY: 50,000 amphetamine-type tablets and 5,000 barbiturate-type capsules, at Covington, Ky., in possession of Paul Anness.

SHIPPED: On unknown dates, from New York, N.Y., and N. Chicago, Ill.

RESULTS OF INVESTIGATION: The seizure was made as the dealer attempted to sell the articles.

LIBELED: 8–27–63, E. Dist. Ky.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and the articles were not exempt from such requirement since they were in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, wholesale distribution, or the dispensing of prescription drugs, and since such articles were not to be dispensed as required by 503(b).

DISPOSITION: 9–27–63. Default—the 25,000 *amphetamine sulfate tablets* and the 5,000 *Nembutal Sodium capsules* actually seized were destroyed.

8013. Amphetamine-containing capsules and tablets and barbiturate-containing capsules and tablets. (F.D.C. No. 48786. S. No. 15–354 V.)

QUANTITY: 273,802 *amphetamine-containing capsules and tablets* and *barbiturate-containing capsules and tablets*, at Oaktown, Ind., in possession of George H. Springstun, M.D.

SHIPPED: Prior to 5–30–63, from outside the State of Indiana.

LIBELED: 5–29–63, S. Dist. Ind.; libel amended 6–5–63.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement since they were prescription drugs, which were not or would not be used nor dispensed by the practitioner in the course of his professional practice in accordance with 503(b).

DISPOSITION: 9–25–63. Default—4 bottles delivered to the Food and Drug Administration; remainder destroyed.

8014. Pyrabate dipyrone injection. (F.D.C. No. 49224. S. No. 86–615 V.)

QUANTITY: 197 individually ctnd. 30-cc. vials, at Atlanta, Ga.

SHIPPED: 10–22–62, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Ctn.) "Multiple Dose Vial Pyrabate Dipyrone Each 2 cc. contains 15 grains (1.0 Gm.) Distributed by RX Dupont Inc. Atlanta, Ga. * * * Caution * * * Contains Chlorobutanol 0.5% For Intramuscular or Intravenous Use."

ACCOMPANYING LABELING: Carton insert entitled "Dipyrone Tablets and Injection Composition * * * Action & Uses."

RESULTS OF INVESTIGATION: Investigation disclosed that the labeling of the article failed to give the reason for having a complete blood count done weekly when the drug was administered in large doses or for prolonged periods of time and failed to specify in full detail the "usual precautions" for the article, as is required by regulations concerning full disclosure of contraindications and precautions.

LIBELED: On or about 8–20–63, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since its labeling failed to conform to the requirements of regulations that its labeling bear adequate information for its use, including relevant hazards and contraindications, under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 9–16–63. Default—destruction.

8015. Pyrodyn tablets and injections. (F.D.C. No. 49110. S. No. 70–503 V.)

QUANTITY: 20 100-tablet btls. of *Pyrodyn tablets* and 31 30-cc. vials and 2,720 2-cc. vials of *Pyrodyn injection*, at Nashville, Tenn.

SHIPPED: Between 11–13–61 and 7–9–63, from St. Louis, Mo., by Shaw Pharmacal Co., and from Decatur, Ill., by Taylor Pharmacal Co.

LABEL IN PART: (Btl.) "Pyrodyn Each tablet contains Methampyrone Sodium 0.5 Gm. * * * Manufactured for Phillips Laboratories, Inc., Nashville, Tenn."; (30-cc. vial) "Pyrodyn 50 Per Cent Solution * * * Methampyrone Sodium Pyrodyn 0.5 Gram per cc. in water for injection * * * Manufactured for Phillips Laboratories, Inc. Nashville, Tenn."; and (2-cc. vial) "Pyrodyn 2 cc. ampul Each 2 cc. contains Methampyrone Sodium 1 gram * * * in water for injection * * * Manufactured for Phillips Laboratories, Inc., Nashville, Tenn."

ACCOMPANYING LABELING: Loose labels shipped with the articles.

LIBELED: 7–15–63, M. Dist. Tenn.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement since their labeling failed to conform to the requirements of the exempting regulations.

DISPOSITION: 9–12–63. Default—destruction.

8016. Di-Po tablets. (F.D.C. No. 49228. S. No. 45–395 V.)

QUANTITY: 65,610 tablets in bulk drums and 105 100-tablet btls., at Little Rock, Ark., in possession of Gateway Laboratories, Inc.

SHIPPED: 9–5–61, from Culver City, Calif.

LABEL IN PART: (Btl.) "Di-Po Analgesic-Antipyretic Each sugar coated tablet contains: * * * Caution: Federal law prohibits dispensing without prescription * * * Gateway Laboratories, Inc. Little Rock, Arkansas."

ACCOMPANYING LABELING: Bottle inserts entitled "Di-Po Buffered Methampyrone Sodium * * * Indications: For use as an analgesic and antipyretic."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and in the usual course of business was repacked by the dealer into the bottles as described above.

LIBELED: 8–19–63, E. Dist. Ark.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since the labeling on or within the package failed to bear, as required by the exemption regulations for prescription drugs, adequate information for its use under which practitioners licensed to administer the drug could use the article safely and for the purposes for which it was intended.

DISPOSITION: 9–24–63. Default—destruction.

8017. Hexol germicide. (F.D.C. No. 48656. S. Nos. 55–605/8 V.)

QUANTITY: 142 2-oz. btls., 142 6-oz. btls., 142 12-oz. btls., and 118 24-oz. btls., at Kansas City, Mo.

SHIPPED: 10–18–62 and 1–14–63, from Colorado Springs, Colo., by Hexol, Inc.

LABEL IN PART: (Btl. and ctn.) "Hexol * * * Germicide Antiseptic-Deodorant For Bathroom Feminine Hygiene Baby Care * * * Hexol Inc., San Francisco, California."

LIBELED: On or about 3–1–63, W. Dist. Mo.

CHARGE: 502(f)(2)—when shipped, the labeling of the article failed to bear a warning that the article was not to be used as a douche more often than twice weekly unless directed by a physician; and a statement cautioning that in case of deep, or puncture wounds, or serious burns, a physician should be consulted; and that if redness, irritation, swelling, or pain persisted or increased or infection occurred, use of the article was to be discontinued and a physician consulted.

DISPOSITION: 4–5–63. Default—destruction.

8018. Sauna bath device. (F.D.C. No. 49773. S. No. 59–352 X.)

QUANTITY: 20 devices, at Los Angeles, Calif., in possession of Trans Western Associates.

SHIPPED: Between 10–4–63 and 12–9–63, from Bruce Crossing, Mich.

ACCOMPANYING LABELING: Leaflets entitled "Private Sauna Wire Telegram," "Architects Builders," and "The Selhinki Nippa Sauna Finnish Bath"; and reprints entitled "Finnish Tranquilizer The Sauna" (from Town and Country Magazine, March 1963), and "The Sauna: A New Dimension in Bathing" (from House Beautiful Magazine of August 1961).

RESULTS OF INVESTIGATION: The accompanying labeling had been printed locally for the purpose of promotion of sales of the article. Examination indicated that the device consisted of a heat-producing stove, either 220-volt electrical or gas, which was surrounded by rocks.

LIBELED: 2–7–64, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for relieving strife and tension, hangover, deep cleansing of the body and mind, rejuvenation and speeding bodily processes, returning lost functions of the joints and skin pores; and in the treatment and prevention of arthritis, sinus, acne and other skin problems; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 3–30–64. Consent—claimed by Fred Glusman, t/a Trans Western Associates, of Los Angeles, Calif., for relabeling.

8019. Ionitron Air Charger. (F.D.C. No. 49240. S. No. 37–310 X.)

QUANTITY: 144 devices, at New Orleans, La., in possession of Philco Distributors, Inc.

SHIPPED: 5–12–61 and 6–13–61, from Philadelphia, Pa., by Philco Corp.

LABEL IN PART: (Ctn.) "Philco * * * Ionitron Kit 61 Air Conditioner Philco Corporation—Accessory Division Phila., Pa., Cincinnati, Ohio, Nashville, Tenn., San Francisco, Calif.," and (device) "Philco * * * Ionitron Kit * * * Philco Corporation * * * Phila., Pa."

ACCOMPANYING LABELING: Booklets entitled "Introducing Your New Ionitron Air Charger * * * Installation * * * Operation * * * Philco Standard Warranty * * * Philco Corporation Philadelphia 34, Penna."; and cards reading in part "Factory Warranty * * * Philco Ionitron."

RESULTS OF INVESTIGATION: Inspection indicated that the device consisted of electronic components (transformer, tubes, capacitors, resistor, etc.) to produce a high voltage which was applied to a fine wire causing the production of negative ions.

LIBELED: 9–3–63, E. Dist. La.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was a revolutionary new approach to health and comfort by enriching the air with ions, thereby making the air more invigorating and work easier; that it increased productivity, improved dispositions, provided immediate and effective relief to sufferers from hay fever and other airborne allergies; and that it was health guarding, and would provide desired relief from heart conditions, sinusitis, asthma, allergy, rose fever, neuralgia, and arthritis; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment, prevention, and relief of asthma, hay fever, and other allergies, conditions for which the article was offered in newspaper advertisements.

DISPOSITION: 1–29–64. Default—7 kits delivered to the Food and Drug Administration, and the remainder destroyed.

8020. Med-O-Solix device. (F.D.C. No. 49342. S. No. 51–763 V.)

QUANTITY: 1 device at Medford, Oreg.

SHIPPED: In September 1961, from Vallejo, Calif., by Gordon Brown Co.

LABEL IN PART: "Med-O-Solix * * * Mfg. by Gordon Brown Co. Vallejo, Calif."

RESULTS OF INVESTIGATION: The device was encased in a green, enameled, metal box, approximately 11½ inches wide, 7 inches high, and 8¾ inches deep. The box contained electrical circuits providing a pulsed, galvanic current to a solenoid coil suspended by a retractable arm attached to the box.

LIBELED: 9–27–63, Dist. Oreg.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and directions for its use could not be written since it was worthless for any medical purpose.

DISPOSITION: 12–13–63. Default—delivered to the Food and Drug Administration.

8021. Auto-Electronic Radioclast device. (F.D.C. No. 49116. S. No. 57–138 T.)

QUANTITY: 1 device, at Bryan, Tex., in possession of Charles E. Moore.

SHIPPED: On an unknown date, from Tiffin, Ohio.

RESULTS OF INVESTIGATION: Investigation indicated that the device was a console-type instrument intended for use by the dealer in diagnosing disease. Its electronic elements included a series of variable resistors, a group of coils, a power supply, and amplifier, and/or occillator unit, and a bakelite plate indicator. The control panel contained switches, meter, timer, and electrode terminals. It was worthless for any medical use, and it was not feasible to devise any labeling that would give adequate directions for use.

LIBELED: 8–23–63, S. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the article failed to bear adequate directions for use, and it was not exempt from such requirement.

DISPOSITION: 10–9–63. Default—destruction.

8022. Halox therapeutic generator. (F.D.C. No. 48221. S. No. 40–549 T.)

QUANTITY: 3 devices, at Summit, N.J., in possession of Anthony Caporaso.

SHIPPED: 9–18–45, from Freeport, Ill., and, on an unknown date, from Central, N. Mex., by the dealer.

LABEL IN PART: (Control panel) "Halox Therapeutic Generator."

ACCOMPANYING LABELING: Books entitled "The Miracles of Father Aull"; pamphlets entitled "The Father Aull Foundation San Francisco, Cal. Oakland, Cal." and "Father Aull Foundation Non Sectarian Central, New Mexico."

RESULTS OF INVESTIGATION: The labeling and photographs indicated that the article was designed as a portable cabinet containing components capable of producing chlorine gas from table salt by means of electrolysis.

LIBELED: 10–18–62, Dist. N.J.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use in overcoming various disease conditions for which the article was recommended, and it was not feasible to devise adequate directions for use, since the article, as designed, was worthless for any medical purpose.

DISPOSITION: 10–28–63. Default—delivered to the Food and Drug Administration.

8023. Magnetron device. (F.D.C. No. 49202. S. No. 18–281 X.)

QUANTITY: 1 unlabeled device at Plainview, Tex.

SHIPPED: 2–9–62, from Lewiston, Idaho, by Peter D. Pauls, D.O.

RESULTS OF INVESTIGATION: Examination indicated the device to consist of a plywood cabinet approximately 2 feet high, 1 foot deep, and 1½ feet wide, containing a drawer at the bottom in which to store two electrodes— a pad type and a probe type. There is a control panel at the front of the device, containing two electrode jacks, a fuse, toggle switch, rheostat knob, and a neon tube.

LIBELED: 8–19–63, N. Dist. Tex.

CHARGE: 502(b)(1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacurer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement in that adequate directions for use cannot be given since the prospective user may be subjected to hazardous electrical shock, under any conditions of use, due to faulty design of the article, and the article is worthless for any medical purpose.

DISPOSITION: 11–13–63. Default—delivered to the Food and Drug Administration.

8024. **Micro-Tabulometer device.** (F.D.C. No. 49948. S. No. 85–103 A.)

QUANTITY: 1 device at Camden, N.J.

SHIPPED: On or about 11–20–63, from Jacksonville, Fla., by Barry L. Ellin.

LABEL IN PART: (Front of device) "Rx Micro-Tabulometer."

RESULTS OF INVESTIGATION: Inspection indicated that the device consisted of a white-finished wood cabinet containing a series of electrical bridge circuits, a large panel ammeter, a series of toggle switches with a hand electrode, and a probe applicator. It was intended for use in medical diagnosis to indicate variations in skin resistance along the spinal column.

LIBELED: On or about 3–24–64, Dist. N.J.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for its intended uses, namely, to locate nerve interferences and for diagnosis; and it was not feasible to write such directions since the device was worthless for any medical purpose.

DISPOSITION: 5–15–64. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

8025. **Ferascorb tablets.** (F.D.C. No. 49912. S. No. 12–182 A.)

QUANTITY: 9 ctns., containing a total of approximately 248,125 tablets, and 175 100-tablet btls., at Brighton, Mass., in possession of Lexington Chemical Co.

SHIPPED: 1–20–64, from Long Island City, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Ctn.) "Ferrous Sulfate w/Ascorbic Acid Tabs * * * Robin Pharmacal Corp. L.I. City, N.Y.," and (btl.) "Each Tablet Contains: Ferrous Sulfate Exic. 30 Mgms. Ascorbic Acid 200 Mgms. * * * Dosage * * * Caution * * * Lexington Chemical Co. Boston Mass."

RESULTS OF INVESTIGATION: The article was shipped in bulk cartons and repacked in part into the bottles labeled as described above, by the dealer.

Analysis showed that the article contained 71 percent of the declared exsiccated ferrous sulfate.

LIBELED: 3–10–64, Dist. Mass.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the treatment of iron deficiency anemias.

DISPOSITION: 4–21–64. Consent—claimed by Lexington Chemical Co., and relabeled.

8026. **Carenol Elixir.** (F.D.C. No. 49129. S. No. 59–858 V.)

QUANTITY: 142 1-pt. btls. at Coral Gables, Fla.

SHIPPED: 1–3–63, from Evanston, Ill., by Bexell Associates, Inc.

*See also Nos. 8009, 8010.

LABEL IN PART: (Btl.) "Carenol Elixir Sedative and antispasmodic Manufactured for M.A.S. Pharmaceuticals, Inc. Coral Gables Florida Each teaspoonful (5 cc.) contains: Phenobarbital ¼ gr."

RESULTS OF INVESTIGATION: Analysis showed that the article contained no phenobarbital.

LIBELED: 7–24–63, S. Dist. Fla.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Each teaspoonful (5 cc.) contains: Phenobarbital ¼ gr." was false and misleading.

DISPOSITION: 1–6–64. Default—destruction.

8027. **Rubber prophylactics.** (F.D.C. No. 49239. S. No. 1-068 X.)

QUANTITY: 50 ctns., each containing 72 2-unit pkgs., at Wildwood, Fla.

SHIPPED: 7–11–63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Tops Prophylactics * * * M & M Rubber Co. Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 2.3 percent of the article contained holes.

LIBELED: 9–13–63, M. Dist. Fla.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess.

DISPOSITION: 10–16–63. Default—destruction.

8028. **Rubber prophylactics.** (F.D.C. No. 49236. S. Nos. 808/9 X.)

QUANTITY: 100 ctns., each containing 72 2-unit pkgs., at Wildwood, Fla.

SHIPPED: 3–5–63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics Package of Two M & M Rubber Co., Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 2 percent of the articles contained holes.

LIBELED: 9–13–63, M. Dist. Fla.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease only" was false and misleading as applied to a product containing holes.

DISPOSITION: 10–16–63. Default—destruction.

8029. **Rubber prophylactics.** (F.D.C. No. 48756. S. No. 55–592 V.)

QUANTITY: 125 gross, unlabeled, at Kansas City, Kans.

SHIPPED: 3–25–63, by De Caribe Rubber Co., Carolina, P.R.

RESULTS OF INVESTIGATION: Examination of the article showed that approximately 2.0 percent were defective in that they contain holes.

LIBELED: On or about 4–25–63, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess.

DISPOSITION: 12–5–63. Default—destruction.

8030. Rubber prophylactics. (F.D.C. No. 49353. S. No. 41–370 X.)

QUANTITY: 7 20-gross ctns. at New York, N.Y.

SHIPPED: 5–31–63, from Akron, Ohio, by Killashun Sales Div. of The Akwell Corp.

LABEL IN PART: (Unit foil wrapper) "Sultan One Lubricated Prophylactic * * * Sold For Prevention of Disease Only * * * Mfd. by The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that approximately 1 percent of the article was defective in that it contained holes.

LIBELED: 10–14–63, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements "Assists in protecting health through the prevention of venereal disease and the reinfection of the female with trichomonas," "Sold for the prevention of disease only," and "Sold For Prevention Of Disease Only" were false and misleading as applied to a product containing holes.

DISPOSITION: 12–12–63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

8031. Imitation Dexamyl Spansule capsules and imitation Dexedrine Spansule capsules. (F.D.C. No. 49461. S. Nos. 12–648/9 X.)

QUANTITY: 164 250-capsule btls. of *imitation Dexamyl Spansule capsules* and 5 250-capsule btls. of *imitation Dexedrine Spansule capsules*, at Chicago, Ill.

SHIPPED: 8–1–63, from Tenafly, N.J., by Howard Press.

LABEL IN PART: (Btl.) "Dexamyl Spansule (No. 2) Smith Kline & French Labs. Philadelphia, Pa."; (btl.) "15 mg. Dexedrine Spansule Smith Kline & French Labs. Phila. Pa."

LIBELED: 10–11–63, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the label designations "Dexamyl Spansule" and "Dexedrine Spansule" were false and misleading as applied to products which did not consist of Dexamyl Spansule capsules and Dexedrine Spansule capsules manufactured by Smith, Kline & French Laboratories, but did consist of *imitaton Dexamyl Spansule capsules* and *imitation Dexedrine Spansule capsules;* 502(i)(2)—the articles were imitations of other drugs; and 502(i)(3)—the articles were offered for sale under the names of other drugs.

DISPOSITION: 12–9–63. Default—delivered to the United States attorney.

8032. Imitation drugs. (F.D.C. No. 49391. S. Nos. 12–650/2 X.)

QUANTITY: 24 cases, each containing 12 250-capsule btls. of *imitation Dexamyl Spansule capsules*, 12 cases, each containing 12 250-capsule btls. of *imitation Dexedrine Spansule capsules*, and 2 bags, containing a total of 3,000 capsules designated as *Mysteclin-F*, at Chicago, Ill.

SHIPPED: 10–6–63, from Union, N.J., by Howard Press.

LIBELED: 10–7–63, N. Dist. Ill.

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*See also Nos. 8007–8010, 8018, 8019, 8025, 8026, 8028, 8030.

CHARGE: 502(a)—when shipped, the label designations "Dexamyl Spansule" and "Dexedrine Spansule" were false and misleading; 502(i)(2)—the articles were imitations of other drugs; and 502(i)(3)—the articles were offered for sale under the names of other drugs.

DISPOSITION: 10–31–63. Default—delivered to the United States attorney.

8033. Clusivets tablets and Clusivol capsules. (F.D.C. No. 49384. S. Nos. 12–642/3 X.)

QUANTITY: 1,440 100-tablet btls. of *Clusivets* and 1,995 100-capsule btls. of *Clusivol*, at Niles, Ill.

SHIPPED: 6–7–63, from Rouses Point, N.Y., by Ayerst Laboratories, Inc.

LABEL IN PART: (Btl. and ctn.) "Clusivets For The Entire Family Multiple Vitamins-Minerals Dosage * * * Ayerst Laboratories Incorporated," and "Clusivol For Adults Potent Nutritional Safeguard Rich in Vitamins with Essential Minerals Dosage * * * Ayerst Laboratories Incorporated."

ACCOMPANYING LABELING: Package inserts entitled "Insure Better Health For The Entire Family."

LIBELED: 10–11–63, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of conditions due to increased body stress, eye disturbances, infections, fatigue, skin disorders, and respiratory infections; to maintain strong, healthy skin structure; build the blood; stimulate the appetite; strengthen the nervous system; promote digestion; promote healthy gum structures and strong bones; promote growth; and to stimulate wound healing and tissue repair.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 11–18–63. Consent—claimed by American Home Products Corp. for relabeling.

8034. Various prescription drugs. (F.D.C. No. 46047. S. Nos. 84–398/400 R, 91–721/9 R.)

QUANTITY: 9 ctns. of various quantities of prescription drugs, at Fort Lee, N.J., in possession of Shames & Gerringer.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: "Professional Sample," "Complimentary," and "For Clinical Use," or similar wording.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs which were originally intended for use as samples, and were still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of New Jersey.

LIBELED: 6–26–61, Dist. N.J.

CHARGE: 502(a)—while held for sale, the sample legends on the labels of a number of the articles were false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 8–8–61. Default—destruction.

8035. Beauty Team. (F.D.C. No. 49519. S. No. 78–107 X.)

QUANTITY: 20 ctns., each containing 2 1¾-oz. btls., at San Jose, Calif., in possession of Universal Distributors.

SHIPPED: 10–4–60, from Berne, Switzerland, by Kolb & Grimm.

LABEL IN PART: (Ctn.) "Beauty Team contains Placenta * * * Kolb & Grimm—Phosa-Kosmetik Koniz-Berne Switzerland"; (btl.) "Beauty Team Day [or "Night"]"; and (sticker label on btls.) "Universal Distributors 1521 Hedding San Jose 26, California Swiss Product."

ACCOMPANYING LABELING: Leaflets entitled "Keep Your Youthful Appearance With Beauty Team" and "This is a reprint from 'Let's Live' Magazine July 1963 it's new! * * * Rejuvenating Skin Oil."

RESULTS OF INVESTIGATION: Examination showed that *Beauty Team Night* was a yellowish liquid and *Beauty Team Day* was a pink emulsion.

Investigation showed that the articles were shipped to Mrs. Ora Dooley, in Hollister, Calif., who subsequently sold them to the dealer with the leaflets entitled "Keep Your Youthful Appearance With Beauty Team." These leaflets and the above reprint leaflets were used by the dealer in promoting sales of the articles.

LIBELED: 11–19–63, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for removing wrinkles and crow's-feet; to revitalize dry, loose skin; remove disfiguring skin scars; rejuvenate the skin; increase cellular respiration; form rejuvenating hormones; and prevent abdominal lines after confinement.

DISPOSITION: 1–13–64. Default—destruction.

8036. Dried Swiss whey. (F.D.C. No. 48481. S. No. 21–116 V.)

QUANTITY: 3 cases, each containing 12 1-lb. bags, and 6 cases, each containing 6 2-lb. bags, at Bountiful, Utah, in possession of Clinton Wheat Shop.

SHIPPED: 9–26–62, from Thayne, Wyo.

LABEL IN PART: (Bag) "Dried Swiss Whey * * * Clinton Wheat Shop—Bountiful, Utah."

RESULTS OF INVESTIGATION: The article had been shipped from Wyoming, in bulk 100-lb. bags, to a firm in Salt Lake City, Utah, where it had been repacked into small bags, as described above, which had been supplied by the dealer; and on 10–26–62, the article had been reshipped to the dealer.

LIBELED: 12–12–62, Dist. Utah.

CHARGE: 502(a)—while held for sale, the repack-bag label contained false and misleading representations that the article was adequate and effective to promote health, intestinal management, growth of friendly bacteria, suppress putrefaction in the intestinal tract, promote normal elimination without laxative action, digestion, counteract acidosis (acid stomach), sweeten the intestinal tract, and that the article was an intestinal tonic.

DISPOSITION: 12–18–63. Consent—claimed by Clinton R. Miller, of Washington, D.C., for relabeling.

8037. Tox-Eliminator device. (F.D.C. No. 49363. S. No. 10–469 X.)

QUANTITY: 2 devices and accessories at Newark, N.Y.

SHIPPED: 7–12–63, from Glendale, Calif., by Tox-Eliminator Manufacturing Co.

LABEL IN PART: (Device) "Tox-Eliminator Tox-Eliminator Mfg. Co. * * * Glendale 6, Calif."

ACCOMPANYING LABELING: Leaflets entitled "An adventure in living: The Daily Enema or Colonic, by Maurice H. Kowan, B.S., D.O. Reprint from Let's Live," "An adventure in living: Why the Colon is so Important, by Maurice H. Kowan, B.S., D.O. Reprint from Let's Live," and "World's Finest Colonic Irrigation Machine"; brochures entitled "A Money Making Opportunity in The Field of Colonic Therapy," and testimonial and other letters.

RESULTS OF INVESTIGATION: The device consisted of a system of tubes, nozzles, pipes, and valves to be connected to the water plumbing for the production of a glorified enema. The device also included a chair, stool, and table.

LIBELED: 9–30–63, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the name of the article and statements in its labeling were false and misleading since they represented and suggested that the article was adequate and effective for the treatment of high blood pressure, arthritis, rheumatic fever, sinusitis, habitual abortion, colitis, ulcers, skin disorders, toxemia, and other medical conditions.

DISPOSITION: 3–23–64. Default—destruction.

8038. Jayne Mansfield Health-Tan Sun Lamps. (F.D.C. No. 49643. S. Nos. 3–849/50 X.)

QUANTITY: 66 ctns., containing unassembled parts, and 24 ctns., each containing 1 assembled device, at Richmond, Va.

SHIPPED: Between 3–20–63 and 5–6–63, from New York, N.Y., and Bridgeport, Pa., by Celebrity Merchandisers, Inc., and Castelli Engineering Co.

LABEL IN PART: (Ctn.) "Jayne Mansfield Health-Tan Sun Lamp Can't Burn Celebrity Merchandisers, Inc., * * * New York 3, N.Y."; (bulb) "Health-Tan Sunlamp Richmond, Va. U.S.A."; (2 filters) "Can't Burn Health-Tan Sunlamp filter * * * Jayne Mansfield, Richmond, Va."; (3 filters) "Health-Tan Clear Tanning Filter, maximum exposure not more than 15 minutes, Jayne Mansfield, Richmond, Va."; and (ctn.) "Castelli Engineering Co. Bridgeport, Penna. To Frank G. Parker, 371 Lexington Rd., Richmond, Va. Jayne Mansfield Health-Tan Sunlamp Richmond, Va."

ACCOMPANYING LABELING: Brochures reading in part "Safe * * * Jayne Mansfield Patented Health-Tan Sunlamp with exclusive 'Can't Burn' Feature!" and "Operating Instructions"; 4-foot cardboard floor displays and smaller cardboard counter displays, reading in part "Jayne Mansfield Health-Tan Sunlamp with exclusive 'can't burn' feature"; and brochures reading in part "Safe, the only Sunlamp that guarantees protection against over-exposure Jayne Mansfield Patented Health-Tan Sunlamp."

RESULTS OF INVESTIGATION: Examination showed that the article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and holder for the Mylar and/or acetate filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: On or about 12–17–63, E. Dist. Va.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the device was an adequate and effective treatment for relieving tired back, stiff neck, arthritic-like pains, skin problems, aching muscles, and for toning the skin; that the filter would

permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the device could be used as a "sun lamp that can't burn."

DISPOSITION: 1–29–64. Default—delivered to the Food and Drug Administration.

8039. **Safe-T-Sun Lamp.** (F.D.C. No. 49746. S. No. 67–145 X.)

QUANTITY: 1 assembled device, and 33 unassembled devices, in 66 ctns. (2 ctns. for each device), at Silver Spring, Md.

SHIPPED: 11–11–63, from Bridgeport, Pa., by Richard Kastner Co., Inc.

LABEL IN PART: (Sun lamp) "Safe-T-Sun Health Tan Sun Lamp"; and (filter) "Safe-T-Sun Corporation Health-Tan Sun Lamp Williamsburg-Virginia."

ACCOMPANYING LABELING: Pamphlets reading in part "Yes! This is the amazing new Safe-T-Sun Health-Tan Sun Lamp that Can't Burn."

RESULTS OF INVESTIGATION: Examination showed that the article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: On or about 1–29–64, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the treatment of adolescent and other skin problems, relieving tired back, arthritic- and rheumatic-like pains, chills, stiff neck and back; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning, and that infants could be exposed for hours without the slightest harm; and that the device could be used as a "sunlamp that can't burn."

DISPOSITION: 3–4–64. Default—destruction.

8040. **Safe-T-Sun Lamp.** (F.D.C. No. 49753. S. No. 16–178 X.)

QUANTITY: 29 unassembled devices at Cincinnati, Ohio.

SHIPPED: 11–27–63, from Bridgeport, Pa., by Richard Kastner Co., Inc.

LABEL IN PART: (Filter) "Safe-T-Sun Corporation."

ACCOMPANYING LABELING: Pamphlet entitled "Yes! This is the amazing new Safe-T-Sun Health-Tan Sun Lamp that Can't burn."

RESULTS OF INVESTIGATION: The article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: 1–29–64, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the treatment of adolescent and other skin problems, relieving tired back, arthritic- and rheumatic-like pains, chills, stiff neck and back; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning, and that infants could be exposed for hours without the slightest harm; and that the device could be used as a "sunlamp that can't burn."

DISPOSITION: 3–10–64. Default—4 devices, with pamphlets, delivered to the Food and Drug Administration and remainder destroyed.

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Jayne Mansfield Health-Tan Sun Lamps 8038

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Beauty Team	8035
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Zirin Laboratories International, Inc.:	
Cardiobee 15 injection	8005

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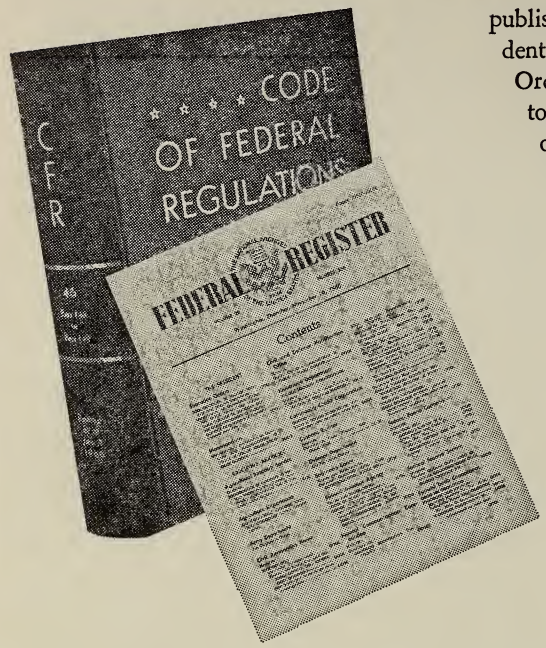

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8041–8080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *July 6, 1965.*

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775–691—65——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8041. (F.D.C. No. 48189. S. Nos. 56-642/3 T.)

INFORMATION FILED: 7-22-63, E. Dist. Tex., against **Joseph P. Riddle, Jr., Henderson, Tex.**

CHARGE: On 1-16-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 7-30-63. Imprisonment for 90 days suspended.

8042. (F.D.C. No. 45554. S. Nos. 5-622/5 R.)

INFORMATION FILED: 5-25-61, Dist. Md., against **John William Scott, Baltimore, Md.**

CHARGE: Between 10-6-60 and 10-10-60, *amphetamine sulfate tablets* (counts 1 and 3), *Seconal Sodium capsules* (counts 2 and 4), and *Dexamyl Spansule capsules* (counts 2 and 4) were each dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: On 11-14-63, after trial by the court on that day, the court found Scott guilty. On 7-2-64, Scott was sentenced to 2 years' imprisonment, which was suspended, and was placed on probation for 2 years.

8043. (F.D.C. No. 48929. S. Nos. 881 V, 59-204/6 V, 59-213 V.)

INFORMATION FILED: 8-30-63, S. Dist. Fla., against **Leevy C. Mears** and **William G. Dexter, Hialeah, Fla.**

CHARGE: Between 12-10-62 and 1-17-63, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Not guilty.

DISPOSITION: On 2-13-64, the case came on for trial before court and jury. On 2-14-64, the jury returned a verdict of guilty against both defendants on all counts. On 4-6-64, each defendant was sentenced to imprisonment for 1 year.

8044. (F.D.C. No. 49541. S. Nos. 54-702/3 V, 18-386/7 X.)

INFORMATION FILED: 4-2-64, N. Dist. Okla., against **Jack Wilkinson, Robert Carmichael,** and **Lee Jones (individuals), Chouteau, Okla.**

CHARGE: Between 12-10-62 and 6-26-63, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Wilkinson to 2 counts and by the other individuals to 1 count each.

DISPOSITION: 5-7-64. Carmichael—$150 fine, and probation for 3 years; Jones—$100 fine, and probation for 3 years; and Wilkinson—probation for 1 year.

8045. (F.D.C. No. 50022. S. Nos. 59-325/6 V, 59-346 V.)

INFORMATION FILED: 5-25-64, M. Dist. N.C., against **Richard L. Turner, Mebane, N.C.**

CHARGE: Between 3-2-63 and 4-8-63, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–2–64. $750 fine, imprisonment for 1 year suspended, and probation for 5 years.

8046. (F.D.C. No. 49179. S. No. 19–915 V.)

INFORMATION FILED: 12–11–63, N. Dist. Tex., against **James Douglas Bogue, Fort Worth, Tex.**

CHARGE: On 3–9–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–7–64. 6 months in prison.

8047. (F.D.C. No. 50011. S. Nos. 62–923/4 V.)

INFORMATION FILED: 5–21–64, S. Dist. Calif., against **Edward Gonzales Romo, Los Angeles, Calif.**

CHARGE: Between 3–27–63 and 4–4–63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 7–14–64. Imprisonment for 2 years suspended, and probation for 5 years.

8048. (F.D.C. No. 50350. S. Nos. 60–441/2 A.)

INFORMATION FILED: 5–28–64, S. Dist. Calif., against **Richard D. Reid and Diane Reid, Gardena, Calif.**

CHARGE: Between 1–11–64 and 1–22–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Richard Reid to 2 counts, and by Diane Reid to 1 count.

DISPOSITION: 7–14–64. Richard D. Reid—$500 fine, imprisonment for 1 year suspended, and probation for 5 years; Diane Reid—$500 fine, imprisonment for 1 year suspended, and probation for 5 years.

8049. (F.D.C. No. 48893. S. No. 1–963 T.)

INFORMATION FILED: 5–7–63, N. Dist. Ga., against **William Hugh Rogers, Doraville, Ga.**

CHARGE: On 12–29–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–16–64. Probation for 2 years.

8050. (F.D.C. No. 49180. S. No. 73–701 V.)

INFORMATION FILED: 2–3–64, E. Dist. Tex., against **Joseph Phillip Devine, D.O., Timpson, Tex.**

CHARGE: On 4–10–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–22–64. $1,000 fine, imprisonment for 1 year suspended, and probation for 3 years.

8051. (F.D.C. No. 50379. S. No. 62–169 A.)

INFORMATION FILED: 7–17–64, S. Dist. Calif., against **Phillip Martin Wilson, San Pedro, Calif.**

CHARGE: On 5–22–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–1–64. Probation for 5 years.

8052. (F.D.C. No. 50027. S. Nos. 17–221 V, 17–228 V, 16–773 X.)

INFORMATION FILED: 8–26–64, S. Dist. Ohio, against **Paul E. Koch, Cincinnati, Ohio.**

CHARGE: Between 1–29–63 and 10–11–63, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–10–64. $450 fine, imprisonment for 1 year suspended, and probation for 1 year.

8053. (F.D.C. No. 50185. S. Nos. 14–950/2 X.)

INFORMATION FILED: 7–27–64, N. Dist. Ill., against **Charles R. Goldstein, t/a City Foot Center, Calumet City, Ill.**

CHARGE: Between 10–1–63 and 10–10–63, *amphetamine sulfate tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–17–64. $250 fine, plus costs, imprisonment for 30 days, and probation for 2 years.

8054. (F.D.C. No. 50356. S. Nos. 15–415/16 X.)

INFORMATION FILED: 9–1–64, S. Dist. Ohio, against **Harvey H. Feazell (truck driver), Roanoke, Va.**

CHARGE: On 10–19–63, in Hamilton County, Ohio, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: The case was transferred to the United States District Court for the Western District of Virginia, and on 10–13–64, the defendant was sentenced to probation for 3 years.

8055. (F.D.C. No. 50346. S. Nos. 14–854 T, 14–856 T, 14–858 T, 14–969 X.)

INFORMATION FILED: 7–27–64, N. Dist. Ill., against **Bernard V. Kobeszka, Calumet City, Ill.**

CHARGE: Between 4–10–62 and 11–5–63, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–13–64. 60 days in prison and probation for 2 years.

8056. **Supplement to notice of judgment on drugs and devices, No. 6409. Violation of probation.** (F.D.C. No. 42482. S. Nos. 66–741/3 R, 12–451/2 T.)

On 6–16–60, upon a plea of nolo contendere to the charge of dispensing *dextro-ampetamine sulfate tablets* 4 times and *amphetamine sulfate tablets* twice without a prescription, and to the charge of conspiring to cause the dispensing of quantities of *amphetamine sulfate tablets and capsules*, the defendant, **Robert Rubin Yablon**, was given a sentence of $700 fine and probation for 3 years.

On 7–30–62, the defendant was brought before the court on a charge of violating his probation by dispensing between 3–15–61 and 12–1–61, *dextro-amphetamine sulfate capsules* 4 times without a prescription. The defendant denied the charge and, after a hearing on the matter, the court revoked the probaton.

On 3–7–63, the court sentenced the defendant to 1 year and 1 day in prison, suspended the sentence, and extended the probation until 6–16–65.

8057. (F.D.C. No. 47333. S. Nos. 19–048 R, 23–823 T.)

INFORMATION FILED: 9–25–62, Dist. Colo., against **Melvin J. Kirby and Herbert W. Young (employees of a truck stop), Lamar, Colo.**

CHARGE: Between 4–6–60 and 11–9–61, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–1–63. Kirby—1 year in prison, 7 months of which was suspended, and probation for 7 months. 7–13–64. Young—5 months in prison.

8058. (F.D.C. No. 49876. S. No. 55–262 A.)

INFORMATION FILED: 3–19–64, S. Dist. Iowa, against **William L. Pennington, Des Moines, Iowa.**

CHARGE: On 1–25–64, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–31–64. 1 year in prison, 10 months of which was suspended, and probation for 2 years.

8059. (F.D.C. No. 50351. S. Nos. 14–384/92 V, 14–394/5 V.)

INFORMATION FILED: 7–27–64, N. Dist. Ill., against **Sheridan-Irving Drug Co. (a corporation), Marcus Fischer (president and pharmacist), and Nathan L. Roseman (vice president and pharmacist), Chicago, Ill.**

CHARGE: Between 1–25–63 and 5–2–63, *dextro-amphetamine sulfate capsules* were dispensed 9 times and *meprobamate tablets* were dispensed twice without a prescription.

PLEA: Guilty by the corporation to all counts; by Fischer to 4 counts; and by Roseman to 7 counts.

DISPOSITION: 9–17–64. Corporation—$1,100 fine; Fischer—$250 fine, plus costs, and probation for 2 years; Roseman—$250 fine, plus costs, and probation for 2 years.

8060. (F.D.C. No. 49195. S. Nos. 6–343 V, 6–345/7 V, 6–565 V, 6–567/70 V, 6–903 V.)

INFORMATION FILED: 1–23–64, Dist. Mass., against **Belson Drug Co., Inc., Brighton, Mass., Irwin H. Springer (president), and Walter Rosenfield (treasurer).**

CHARGE: Between 10–11–62 and 1–14–63, *Dexedrine Sulfate tablets* and *Miltown tablets* were each dispensed 5 times upon request for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–28–64. Corporation—$1,000 fine; each individual—$500 fine.

8061. (F.D.C. No. 50354. S. Nos. 32-016/17 X, 32-019 X, 32-032 X, 32-034 X, 32-130 X, 32-135 X, 32-145 X.)

INFORMATION FILED: 8-3-64, Dist. Ariz., against **Lionel C. Gorosave, t/a Sloan's Pharmacy, Tucson, Ariz.**

CHARGE: Between 9-6-63 and 11-4-63, *Dexedrine Sulfate tablets* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed twice without a prescription, and *Seconal Sodium capsules* were dispensed twice upon request for prescription refills without obtaining authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 10-5-64. $1,750 fine, imprisonment for 1 year suspended, and probation for 2 years.

8062. (F.D.C. No. 50452. S. Nos. 56-223/4 X, 56-231/2 X.)

INFORMATION FILED: 8-31-64, S. Dist. Ohio, against **James P. Culley, t/a Culley Central Pharmacy, Harrison, Ohio.**

CHARGE: Between 11-6-63 and 12-20-63, *Dexedrine Spansule capsules* were dispensed 3 times and *Tuinal capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9-10-64. $400 fine.

8063. (F.D.C. No. 49857. S. Nos. 20-742 X, 20-745/50 X.)

INFORMATION FILED: 4-23-64, W. Dist. Okla., against **Jim M. Hastings (pharmacist), Oklahoma City, Okla.**

CHARGE: Between 8-13-63 and 9-24-63, *Dexedrine Spansule capsules* were dispensed 5 times, and *Seconal Sodium capsules* were dispensed twice, upon requests for prescription refills without obtaining authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9-21-64. $175 fine.

8064. (F.D.C. No. 46383. S. Nos. 35-404 R, 35-408/9 R, 56-502 R, 56-504/5 R, 56-661/2 R, 56-671 R, 56-741/2 R.)

INFORMATION FILED: 6-27-62, E. Dist. N.Y., against **Ralph Baratta, t/a Palmer's Rexall Drug Store, Brooklyn, N.Y., Palmer's Rexall Drug Store, Inc., Richard Swedlow (corporation president and pharmacist), and Howard Schlinger (corporation secretary and pharmacist).**

CHARGE: Between 1-19-61 and 2-20-61, *Equanil tablets*, *secobarbital sodium capsules* and *methyltestosterone tablets* were each dispensed twice, and *dextroamphetamine sulfate capsules* were dispensed once, without a prescription, and *chloramphenicol capsules* were dispensed 3 times, and *secobarbital sodium capsules* were dispensed once, upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Baratta to 1 count involving a refill of *chloramphenicol capsules* and by the corporation to 9 other counts. Nolo contendere by Swedlow to 1 count involving a refill of *chloramphenicol capsules* and to 2 counts which involved the dispensing of *methyltestosterone tablets* once and *secobarbital sodium capsules* once without a prescription, and by Schlinger to 7 other counts.

DISPOSITION: 8-23-62. Baratta—$500 fine; corporation—$45 fine; Swedlow—$300 fine; and Schlinger—$700 fine.

8065. (F.D.C. No. 49532. S. No. 29–374 V.)

INFORMATION FILED: 1–28–64, Dist. Kans., against **Wilford J. Keeling, t/a Keeling Pharmacy, Kansas City, Kans.**

CHARGE: On 1–28–63, *Equanil tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–7–64. $1,000 fine, and imprisonment for 1 year, of which 10 days were to be served and the defendant to be placed on probation for remainder of the year.

8066. (F.D.C. No. 49536. S. Nos. 60–530 V, 60–533 V.)

INFORMATION FILED: 2–26–64, N. Dist. Tex., against **Warren Caperton McCleskey, t/a Hotel Drug, Mineral Wells, Tex.**

CHARGE: Between 4–2–63 and 4–8–63, *prednisone tablets* and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–7–64. 6 months in prison suspended, and probation for 6 months.

8067. (F.D.C. No. 50170. S. Nos. 15–027 X, 15–032 X, 15–743/4 X, 16–533 X, 16–541 X.)

INFORMATION FILED: 8–26–64, S. Dist. Ohio, against **Donald J. Karches, t/a Don's Pharmacy, Cincinnati, Ohio.**

CHARGE: Between 7–8–63 and 8–29–63, *prednisone tablets*, *Miltown tablets*, *Diuril tablets*, *Thorazine tablets*, *Seconal Sodium capsules*, and *Tuinal capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–8–64. $300 fine, imprisonment for 6 months suspended, and probation for 6 months.

8068. (F.D.C. No. 49158. S. Nos. 64–441/50 V.)

INFORMATION FILED: 10–21–63, against **Thomas W. Wood (an individual), Paintsville, Ky.**

CHARGE: Between 1–15–63 and 3–20–64, *prednisone tablets* and *Diuril tablets* were each dispensed 4 times without a prescription, and *Orinase tablets* and *Equanil tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–30–64. $1,000 fine, of which $500 was suspended, probation for 1 year, plus costs.

8069. (F.D.C. No. 46382. S. Nos. 6–389/93 R, 6–827/8 R, 6–842/4 R, 6–859 R.)

INFORMATION FILED: 12–21–61, Dist. Conn., against **Joseph J. Krzanowski, t/a Krzanowski Pharmacy, Hartford, Conn.**

CHARGE: Between 3–10–60 and 5–5–60, *Miltown tablets* were dispensed twice without a prescription, *dextro-amphetamine sulfate capsules* were dispensed 5 times, *Miltown tablets* were dispensed 3 times, and *Equanil tablets* were dispensed once, upon requests for prescription refills without obtaining an authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: On 1–15–62, a motion by the defendant to dismiss the information was argued before the court. On 1–19–62, the court ruled against the defendant as follows:

BLUMENFELD, *District Judge:*

RULING ON MOTION TO DISMISS

"An information filed on December 21, 1961 charged the defendant with violations of 21 U.S.C. § 353(b) and § 331(k), which occurred between March 10 and May 5, 1960. Defendant now moves to dismiss the information and relies upon the Fifth and Sixth Amendments and upon Rule 48(b) of the Federal Rules of Criminal Procedure, 18 U.S.C.A.

"The gravamen of defendant's claims under the Sixth Amendment and Rule 48(b) rests upon his assertion that, since the alleged violations in each case involved the act of dispensing misbranded drugs committed twenty-two months prior to the filing of this information to federal narcotics agents, all the evidence necessary for prosecution was in hand contemporaneously with these sales. The defendant's reliance on the Sixth Amendment is not well-taken. The right to a speedy trial arises only after the filing of a formal complaint. *Hoopengarner* v. *United States* (6 Cir. 1959), 270 F. 2d 465, 469; *D'Aquino* v. *United States* (9 Cir. 1951), 192 F. 2d 338, 350. Defendant's claim here rests solely upon the lapse of time prior to the issuance of a formal complaint. The Sixth Amendment, therefore, would not be applicable. 18 U.S.C.A. Rule 48(b) is merely a contemporary enunciation of that same right to a speedy trial guaranteed by the Sixth Amendment. *United States* v. *Palermo* (D.C. S.D. N.Y. 1961), 27 F.R.D. 393, 394. The rule comes into operation only *after* the defendant has 'been held to answer to the district court.' *United States* v. *Kabot* (D.C. S.D. N.Y. 1960), 185 F. Supp. 159. This defendant was not held to answer prior to the filing of this information. This distinction is also made clear in *Hoopengarner* v. *United States, supra,* at p. 469, where the court stated: 'As to delay from the time of the commission of the offense to the commencement of the criminal proceedings, that is controlled by the Statute of Limitations . . .'

"Although the weight of authority is overwhelmingly contra, if it is assumed that Rule 48(b) extends to the preindictment period, the defendant's showing would be inadequate. He argues that all the evidence necessary for prosecution was compiled at the instant of sale, since the buyers were in fact narcotics agents. The government was still required to obtain evidence to prove that the drugs involved were in fact purchased in interstate commerce.

"Defendant's remaining claim is that the lapse of time would necessarily have dulled the minds of the defendant's witnesses and thereby has made his defense more difficult. This allegation was unsupported by any evidence, and, therefore, is far short of the 'sifted evidence and demonstrated facts' required to support the motion. *United States* v. *Monarch Radio & Television Corp.* (D.C. S.D. N.Y. 1958), 162 F. Supp. 910, 911; *United States* v. *Research Foundation* (D.C. S.D. N.Y. 1957), 155 F. Supp. 650, 654.

"Finally, defendant asserts denial of due process under the Fifth Amendment. The basis for this claim is not ascertainable. Defendant did make a fleeting allegation that these sales were induced and coerced by government agents. That might support a defense based upon entrapment. However, this defense would involve questions of fact and, therefore, its final determination will be deferred until the trial in conformity with Rule 12(b)(4), 18 U.S.C.A.

"The defendant's motion to dismiss is denied.

"Dated at Hartford, Connecticut, this 19th day of January, 1962."

On 3–21–62, the court rendered the following decision on a motion by the defendant for the return of property and to suppress evidence:

CLARIE, *District Judge:*

MEMORANDUM OF DECISION ON
MOTION FOR RETURN OF PROPERTY
AND TO SUPPRESS EVIDENCE

"The information charges the defendant in eleven (11) separate counts with violations of the Federal Food, Drug, and Cosmetic Act. June 25, 1938, c. 675, § 1, 52 Stat. 1040, 21 U.S.C.A. § 301 et seq.

"Five counts (1, 2, 3, 6, 9) charge the defendant with dispensing dextroamphetamine sulfate tablets by the refilling of prescriptions without receiving authorization from the prescriber; three counts (4, 5, 8) charge the dispensing of Miltown tablets by refilling prescriptions without authorization of the prescriber; two counts (7, 10) charge the dispensing of Miltown tablets in an unlabeled box without a doctor's prescription; and one count (1) charges the dispensing of Equ [anil] tablets by refilling a prescription without authorization of the prescriber. All dispensings are alleged to have taken place while the drugs were being held for sale after shipment in interstate commerce; and the commission of such acts resulted in said drugs being misbranded while held for sale, in violation of Title 21 U.S.C.A. § 331(k).

"The present motion raises the question of whether the evidence secured by the government as a result of an inspection of the defendant's records at his drug store premises and subsequent interviews at a conference in Boston, was obtained in violation of the safeguards afforded by the Fourth and Fifth Amendments of the United States Constitution.

"The facts educed at the hearing substantiate the following: on May 11, 1960, the defendant had been a licensed pharmacist for approximately eight years and was the proprietor of a retail drug store in Collinsville, Connecticut. On this occasion two inspectors of the Federal Food and Drug Administration (Department of Health, Education and Welfare) appeared at his store, identified themselves by badges and asked permission to see the books, records, and prescription files. Without objection the defendant immediately consented and cooperated with the inspectors. He admitted that none of the evidence was obtained by threat, trick, fraud or compulsion. The inspectors asked for the information and the defendant gave it without hesitation; he permitted them access to his files and inventory records from which they procured evidence and signed statements regarding their purchase, all of which he now believes may incriminate him. He explained that his previous cooperation was based on his belief that because the agents were inspectors and showed their badges, they were entitled to the information.

"Subsequently, the defendant received a notice in accordance with the provisions of 21 U.S.C.A. § 335 to appear at a hearing in the Boston office of the Food and Drug Administration, at which time he could present any evidence in his own behalf concerning the alleged violations; that if he did not appear, the administrative decision of whether or not to refer the matter to the Department of Justice for prosecution, would be based upon the evidence then available. The defendant voluntarily appeared without counsel, but presented no evidence in his own behalf, except a letter which he had prepared in answer to the notice to appear. This letter admitted culpability and promised to correct the procedures in refilling prescriptions in the future. The hearings officer did not attempt to obtain any evidence from him; however, the defendant orally admitted his violations of the Food and Drug Act, which are in substance the subject matter of the pending criminal information. The present motion seeks to suppress the aforesaid letter, the oral admission made to the hearing officer and any evidence or statements procured from the defendant at the time of the inspection at the store.

"The inspection of the drug store was made pursuant to Sections 372 and 374 of Title 21 U.S.C.A., Sub-Section 372(a) provides in part: 'The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department . . .'.

"Section 374 provides in part:

> 'For the purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are au-

> thorized (1) to enter, at reasonable times, any . . . establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed or held, for introduction into interstate commerce or are held after such introduction, . . .; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such . . . establishment, . . . finished and unfinished materials, containers and labeling therein. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed within reasonable promptness.'

"The conditions precedent set forth in the statutes were complied with; the inspectors presented to the defendant-proprietor their badges of office, credentials and a written notice of inspection. Their original entrance and subsequent investigation was conducted during the normal business day; there was nothing threatening or oppressive about the performance of their official duties. This type of investigation is contemplated by the statute, as a routine procedure for proper disciplinary control of the subject matter of the Act.

> 'No constitutional right is violated by a statute, an ordinance or a regulation providing for the inspection of places of business, dealing with drugs or foods during business hours . . . . [This] section is patterned on Section 3601 (now § 7606) of the Internal Revenue Code, 26 U.S.C.A. Int. Rev. Code § 3601, and the authority exercised under the statute has never been regarded as violative of the guarantees of the Fourth Amendment.' *United States* v. *Crescent-Kelvan Co.*, 164 F. 2d 582, 586 (3 Cir. 1948).

"The claim of the defendant at this time that he acted under duress, because the agents showed him a badge of authority is not tenable. 'That fact alone under the circumstances of the case is not sufficient to constitute duress. In the absence of any threats, intimidation or force, incriminating matter turned over to law enforcement officials by an accused may be used in evidence against him.' *United States* v. *Lyon Drug Co.*, 122 F. Supp. 597, 599 (E.D. Wis. 1954); *United States* v. *Scientific Aids Co.*, 117 F. Supp. 588 (D.N.J. 1954); *United States* v. *Arnold's Pharmacy*, 116 F. Supp. 310 D.N.J. 1953).

"The question of whether consent to a search is voluntary is one of fact. 'It is not enough . . . that the Court believes that a verbal consent was given . . . . The circumstances under which the consent was given must be examined to determine whether it was voluntary or coerced.' *United States* v. *DeVivo*, 190 F. Supp. 483, 486 (E.D.N.Y. 1961).

"In a comparable situation involving an internal revenue audit the court held: 'If the disclosure is voluntary, however, the records turned over in the civil audit may be used without restriction.' *Grant* v. *United States*, 291 F. 2d 227, 229 (2 Cir. 1961).

"The defendant claims that his constitutional rights were violated when the inspectors failed to warn him, before their inspection at the store, that he might be subject to criminal prosecution in the event that incriminating evidence was discovered; also that he should have been similarly warned and advised at the time he was summoned to the administrative conference at Boston. That inasmuch as he was not so warned or advised, any evidence procured constituted an illegal search and seizure and/or forced him to incriminate himself in violation of his constitutional rights and should be suppressed.

> 'It has been expressly held time and again in tax evasion and other criminal cases that it is not essential to the admissibility of statements secured by officers of the law from a defendant that he should be first warned that the information might be used against him in a criminal case, provided that it was voluntarily and understandingly given.' *Turner* v. *United States*, 222 F. 2d 926, 931 (4 Cir. 1955).

"Admissions against interest are a most effective character of testimony. The sole test is the voluntary character of the statement. Even the constitutional protection against self-incrimination is applicable in a criminal prosecution only to involuntary evidence. *Joong Sui Noon* v. *United States*, 76 F. 2d 249, 251 (8 Cir. 1935).

"The court finds that the facts of this case unquestionably support a conclusion that the defendant voluntarily consented to the inspection of his records, files and inventory; and that his letter submitted to the administrative office in mitigation was understandingly and freely given.

"The motion for the return of property and to suppress evidence is denied.

"Dated at Hartford, Connecticut, this 21st day of March, 1962."

On 3–30–62, the defendant having filed on 3–1–62, a motion for a Bill of Particulars, the court issued the following ruling granting the defendant's motion:

BLUMENFELD, *District Judge:*

RULING ON DEFENDANT'S MOTION FOR BILL OF PARTICULARS

"The defendant has been charged in several counts with the sale of misbranded drugs in violation of 21 U.S.C.A. § 331(k). He now moves for a bill of particulars directing the government to furnish the precise dates and times of the alleged offenses and the names of the doctors who issued and the dates of issuance of the prescriptions which defendant is charged with having refilled without authority.

"The government argues that if the complaint conforms to all the minimal pleading requirements of Rule 7(c) and Form 11 of the F.R.C.P., 18 U.S.C.A. then no bill of particulars should issue. This argument was considered and rejected in *United States* v. *Hoff Manufacturing Co.*, D.C. Conn., 1962, Cr. No. 10,587.

"The further argument that this bill seeks to require the government to disclose evidence is also rejected, since the court does not interpret these requests as seeking evidence, but only as seeking clarification of the basic charges. See: *United States* v. *Hoff Manufacturing Co.* (*supra*).

"In *United States* v. *Smith*, D.C. W.D. Mo. W.D., 1954, 16 F.R.D. 372, Justice Whittaker (then a District Judge) pointed out two significant reasons why the government should be required to particularize with specificity the facts upon which a complaint is based. First of all, it should be kept in mind that a defendant in a criminal case has fewer means of discovery than a party to a civil action. Consequently, bills of particulars become, 'most important instruments of justice.' *United States* v. *Smith* (*supra*) at p. 375. Second, and of even greater significance, is the underlying presumption of innocence implicit in all criminal proceedings. Because of this presumption, a defendant must be considered to be totally ignorant of all facts other than those set forth in the complaint. It follows that the defendant should be informed of the precise nature of the charge against him so that he may adequately prepare his defense. *United States* v. *Smith* (*supra*) at p. 375; Followed: *United States* v. *J. M. Huber Corp.*, D.C. S.D. N.Y., 1959, 179 F. Supp. 570, 573; *United States* v. *Wilson*, D.C. S.D. N.Y., 1957, 24 F.R.D. 569, 570.

"The date and time of each offense should be set forth with as much exactitude as is possible.

"The request for the names of doctors and dates of issuance of prescriptions is also granted. The court is aware that bills of particulars should not be granted where they seek facts relating to the defendant's own business activities, and are, therefore, within his own knowledge. See: *United States* v. *Ford Motor Co.*, D.C. D.C., 1959, 24 F.R.D. 65, 69, *harmonizing United States* v. *Smith*, (*supra*). However, upon argument of the motion it was indicated that some ambiguity in the defendant's records surrounded these particular facts. Upon this basis, the court orders the government to supply the defendant with this information.

"The defendant's motion for a bill of particulars is granted.

"Dated at Hartford, Connecticut, this 30th day of March, 1962."

On 4–6–62, the Government furnished the defendant with the Bill of Particulars ordered by the court. On 8–20–62, the defendant moved unsuccessfully to dismiss the information as amended by the Bill of Particulars on the ground that the information as amended did not state facts sufficient to constitute an offense against the United States.

On 9–27–62, the case came to trial before court and jury. On 10–5–62, the jury returned a verdict of guilty, and on 10–29–62, Krzanowski was fined $1,100, placed on probation for 6 months, and a sentence of 6 months' imprisonment was suspended.

8070. (F.D.C. No. 50174. S. No. 86–129 V.)

INFORMATION FILED: 7–15–64, S. Dist. Fla., against **A. & F. R. Corp., t/a Westwood Lake Pharmacy, and Sidney M. Margolis (pharmacist).**

CHARGE: On 4–9–63, *Miltown tablets* were dispensed once upon request for a prescription refill without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 8–21–64. Corporation—$300 fine; Margolis—$200 fine, and probation for 1 year.

8071. (F.D.C. No. 50016. S. Nos. 7–463 V, 7–465 V, 8–982 V, 8–984/7 V, 6–961 X.)

INFORMATION FILED: 8–27–64, Dist. Mass., against **Shephard Pharmacy of Newton, Inc., Newton Center, Mass., Stanley Warren (president and treasurer), and Perry Klayman (pharmacist).**

CHARGE: Between 3–29–63 and 6–3–63, *Miltown tablets* were dispensed 3 times, *Dexedrine Spansule capsules* and *Equanil tablets* were each dispensed twice, and *Seconal Sodium capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–27–64. Corporation—$1,000 fine; Warren—$500 fine; Klayman—$200 fine.

8072. (F.D.C. No. 50015. S. Nos. 19–156 X, 20–121 X, 20–124/29 X.)

INFORMATION FILED: 7–24–64, N. Dist. Tex., against **Owen T. Shipp, t/a Shipp's Drug Store, Lueders, Tex.**

CHARGE: Between 8–19–63 and 10–24–63, *penicillin tablets* were dispensed 4 times, *meprobamate tablets* were dispensed twice, and *Dexedrine Spansule capsules* and *desoxyephedrine hydrochloride tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–23–64. $200 fine, imprisonment for 6 months suspended, and probation for 6 months.

8073. (F.D.C. No. 50370. S. Nos. 18–946 X, 18–952 X.)

INFORMATION FILED: 10–4–64, W. Dist. Tex., against **Quickie Mart, Inc., t/a Mac's Discount Drug No. 1, El Paso, Tex., William C. Prelletz (store manager), and Robert C. Hazell (pharmacist).**

CHARGE: Between 9–16–63 and 9–26–63, *penicillin tablets* and *meprobamate tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by the corporation to 2 counts and by each individual to 1 count.

DISPOSITION: 10–9–64. Corporation—$300 fine; Prelletz—$200 fine; Hazell—$100 fine.

8074. (F.D.C. No. 50372. S. No. 68–724 X.)

INFORMATION FILED: 10–7–64, W. Dist. Tex., against **Quickie Mart, Inc., t/a Mac's Discount Drug No. 3, El Paso, Tex., and Ronald M. Muraida (store manager).**

CHARGE: On 9–16–63, *penicillin tablets* were dispensed once upon request for prescription refill without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 10–9–64. Each defendant fined $400.

8075. (F.D.C. No. 48143. S. No. 25–002 T.)

INFORMATION FILED: 10–15–62, E. Dist. Mich., against **Emil Bacilla, t/a Dix-Ward Drugs, Southgate, Mich.**

CHARGE: On 12–26–61, *Achromycin capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–2–64. $250 fine.

8076. (F.D.C. No. 50384. S. Nos. 88–656/7 V.)

INFORMATION FILED: 8–10–64, S. Dist. Tex., against **Karl F. Benning, t/a Port City Pharmacy & Dry Goods, Port Isabel, Tex.**

CHARGE: Between 5–18–63 and 5–20–63, *Biosulfa tablets* and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–31–64. $50 fine.

8077. (F.D.C. No. 49699. S. Nos. 13–189/90 T, 13–193/4 T, 13–197/200 T.)

INFORMATION FILED: 4–14–64, N. Dist. Ill., against **Samson S. Stern, t/a Stern's Campus Drugs, Chicago, Ill., and Julius Stevenson (apprentice pharmacist).**

CHARGE: Between 6–26–62 and 8–22–62, *Darvon Compound Pulvules* were dispensed 4 times, *dextro-amphetamine sulfate tablets* were dispensed 3 times, and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere by Stern to 8 counts; by Stevenson to 7 counts.

DISPOSITION: 7–2–64. Stern—$800 fine, plus costs; Stevenson—18 months in prison suspended, and probation for 18 months.

8078. (F.D.C. No. 49681. S. Nos. 3–903/8 V, 3–911/12 V, 3–914 V.)

INFORMATION FILED: 7–16–64, Dist. Md., against **Lee's Pharmacy of Furnace Branch, Inc., Glen Burnie, Md., and Harvey Greenberg (president).**

CHARGE: Between 11–30–62 and 1–18–63, *Desoxyn Hydrochloride tablets* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed 5 times, upon request for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere by Greenberg; guilty by the corporation.

DISPOSITION: 8–7–64. Each defendant fined $1,000.

8079. (F.D.C. No. 48550. S. No. 57–343 T.)

INFORMATION FILED: 8–9–63, E. Dist. Okla., against **Central Drug Store (a partnership), Duncan, Okla.**

CHARGE: On 8–16–62, *meprobamate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–23–64. $500 fine.

8080. (F.D.C. No. 50353. S. Nos. 56–261/3 X.)

INFORMATION FILED: 8–6–64, E. Dist. Ky., against **Russell Hager, t/a Hager's Cut Rate, Paintsville, Ky.**

CHARGE: Between 10–22–63 and 11–21–63, *Orinase tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–12–64. $600 fine, plus costs.

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[1] (8056) Violation of probation.
[2] (8042, 8043) Prosecution contested.
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[2] (8042, 8043) Prosecution contested.
[3] (8069) Prosecution contested. Contains rulings and decision of the court

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[2] (8042, 8043) Prosecution contested.

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[1] (8056) Violation of probation.

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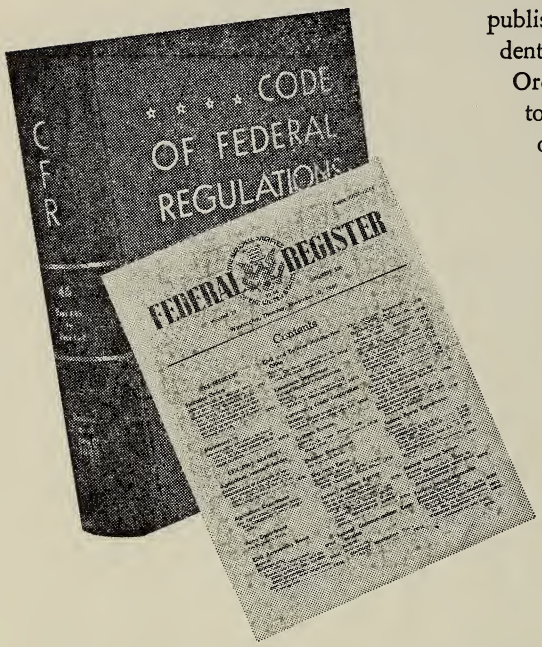

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D.D.N.J., F.D.C. 8081–8140 Issued August 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8081–8140

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, including, in one case, the denials of motions to vacate a default decree and to dismiss the action; (2) criminal proceedings which were terminated upon pleas of guilty or, in one case, upon a judgment of not guilty; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 20, 1965.*

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*For presence of a habit-forming substance without warning statement, see No. 8091; omission of, or unsatisfactory, ingredients statements, Nos. 8091, 8109, 8132; and imitation of, and sale under name of, another drug, No. 8123; failure to bear a label containing an accurate statement of the quantity of the contents, No. 8091; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 8091, 8109, 8118; cosmetics actionable under the drug provisions of the Act, Nos. 8127, 8135.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8081–8140

Adulteration, Section 501(a)(2), the article had been prepared under insanitary conditions whereby it may have been rendered injurious to health; Section 501(a)(2)(A), the article had been held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; Section 501(a)(2)(B), the article was a drug and the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice to assure that such drug met the requirements of the Act as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported and was represented to possess; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance has been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man, and it contained a quantity of the narcotic or hypnotic substance, peyote, and its label failed to bear the name, and quantity or proportion of such substance and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e)(1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502(e)(1)(A), the article was a drug, and its label failed to bear, (i) the established name of the drug, and (ii), in the case where the article was fabricated from two or more ingredients, the established name and quantity of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or some other antibiotic drug, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(1), the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its

label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introducted into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8081. Detoxacolon Therapy device. (F.D.C. No. 50424. S. No. 41–724 A.)

QUANTITY: 1 device at El Paso, Tex.

SHIPPED: On an unknown date in 1948, from Los Angeles, Calif., by United X-Ray & Equipment Co.

LABEL IN PART: (Metal plate on device) "Detoxacolon Therapy Apparatus Model 6 — 864 Serial — United States Patent No. * * * Los Angeles–Kansas City."

ACCOMPANYING LABELING: Manual entitled "DeWelles 'Detoxacolon' Oxygen Therapy Installation of Apparatus and Instruction for Colon Procedures Copyright 1948 by Z. H. & R. W. DeWelles."

RESULTS OF INVESTIGATION: Examination indicated that the device consisted of a pressurized enema device intended for colonic irrigation, to which an oxygen tank was attached. A wall-mounted metal control panel included connections for attachment to a hot- and cold-water supply, 2 inlet valves, an outlet valve, a temperature gauge for controlling the administration of hot and cold water, and a visual water-level gauge. Also included were other component parts such as flexible tubing, a metal pedestal, and a rectal applicator.

LIBELED: 8–4–64, W. Dist. Tex.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for asthma, hay fever, acute coryza, acute sinusitis, colitis, anemia, amebic dysentery, heart conditions, epilepsy, infections and inflammatory diseases of the female pelvis, reducing toxicity during pregnancy, vaginal discharges, tenderness in the pelvis, highly inflamed vaginal areas, high blood pressure, low blood pressure, ballooned rectal and sigmoid area, severe cases of constipation, and elongated descending colon; 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended; and 502(j)—the article was dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

DISPOSITION: 9–30–64. Default—delivered to the Food and Drug Administration.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

8082. Laetrile, Hoxsey treatment, Krebiozen, Mucorhicin, Lincoln treatment, Koch cancer treatment, and Siccacell. (Inj. No. 453.)

COMPLAINT FOR INJUNCTION FILED: 1–23–63, S. Dist. Calif., against Charles Lyle Hawk, M.D., La Canada, Calif., and Willoughby William Sherwood, M.D., West Los Angeles, Calif.

NATURE OF BUSINESS: The complaint alleged that the defendants were physicians licensed to practice medicine in the State of California; that they had

been employees at the Fremont Christian Clinic, Los Angeles, Calif; that they caused an article designated as "*Laetrile*" to be shipped in interstate commerce; that such article bore on its label, the statement: "New drug—limited by Federal law to investigational use"; and that the interstate promotion and distribution of such drug was part of a general scheme for the treatment of cancer by unproven and unorthodox drugs for which there had been no approval of a new-drug application within the meaning of 505.

CHARGE: The complaint alleged that the article, *Laetrile*, was intended for hypodermic injections in the treatment, mitigation, and cure of cancer; that it was a "drug," and was also a "new drug," within the meaning of the Federal Food, Drug, and Cosmetic Act; that it was not generally recognized by qualified experts as safe and effective in the treatment, mitigation, and cure of cancer, for which purposes it was intended; that *Laetrile* was a synthetic chemical for which there had been no approval of a new-drug application under 505; that the composition of *Laetrile* might be expressed in the following way: "Sodium 1 – Mandelonitrile – Beta – Glucuronoside"; and that the defendants caused interstate shipments of *Laetrile* to be made to persons who were not qualified to receive the drug for investigational use, under the provisions of 505(i) and the regulations thereunder.

The complaint alleged further that the Government believed, that unless restrained, the defendants would continue to violate the law by causing to be delivered for introduction into interstate commerce and to be held for sale after shipment in interstate commerce, *Laetrile*, or similar drugs, or drugs intended for similar purposes, which were in violation of the new-drug provision of the law, 505, or which were misbranded within the meaning of 502(a) or 502(f)(1) in that the labeling of such drugs contained false and misleading statements and failed to bear adequate directions for use.

DISPOSITION: On 1–25–63, the defendants having consented, the court entered a permanent injunction enjoining the defendants, their agents, employees, representatives and all other persons in active concert or participation with them, from causing *Laetrile*, or any similar drug, or any other drug with the same name, or any drug intended for similar purposes, to be delivered for introduction into interstate commerce, or to be held for sale after shipment in interstate commerce, in violation of the law, by reason of being misbranded in that the labeling of such drug contained false or misleading statements or failed to bear adequate directions for use, or by reason of being a new drug for which approval of a new-drug application was not effective.

The defendants, and all other persons in active concert or participation with them, were further enjoined from doing any of the following acts since such acts were part of or ancillary to the above violations:

(1) Using, promoting, propagating, dispensing, or participating, in the employment of the drug, *Laetrile*, or any similar drug or any other drug with the same name, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(2) Using, promoting, propagating, dispensing, or participating in the employment of, the so-called *Hoxsey treatment*, containing ingredients such as potassium iodide, licorice, red clover tops, stillingia root, berberis root, poke root, buckthorn bark and pepsin, burdock root, cascara sagrada, prickly ash bark and buckthorn bark, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(3) Using, promoting, propagating, dispensing, or participating in the employment of, the drug, *Krebiozen*, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(4) Using, promoting, propagating, dispensing, or participating in the employment of, the drug, *Mucorhicin*, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(5) Using, promoting, propagating, dispensing, or participating in the employment of, the so-called *Lincoln treatment*, or other bacteriophage, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(6) Using, promoting, propagating, dispensing, or participating in the employment of, Glyoxylide, benzoquinone, or any other similar drug employed as part of the so-called *Koch cancer remedy* or any other drug bearing the designation "Koch," in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(7) Using, promoting, propagating, dispensing, or participating in the employment of, the drug, *Siccacell*, in the treatment, cure, mitigation, prevention, or palliation of cancer or any other disorder.

(8) Using, promoting, propagating, dispensing, or participating in the employment of, any drug which bears the following statement or any similar treatment upon its label: "Caution: New drug—Limited by Federal law to investigational use."

(9) Participating in any promotion, propagation, or advertisement relating to commercial distribution of any drug, device, food, or cosmetic, by endorsement, testimonial, affidavit, or any other means.

8083. Wobe enzymes and prepared animal tissues. (F.D.C. No. 49645. S. Nos. 77–543/53 X.)

QUANTITY: 1,135 ampuls of *Wobe enzymes* and 104 ampuls of *prepared animal tissues*, at New York, N.Y.

SHIPPED: On various unknown dates after 1–1–59, from Vienna, Austria, by Sanabo, from Zurich, Switzerland, by Pharmakon A G, and from Heidelberg, Germany, by Rhein-Chemie.

LABEL IN PART: "Wobe-Mucos 100 mg. Sanabo," "Wobe '2' Enzymes 100 mg. [or "50 mg."] nach Prof. Dr. Wolf Sanabo-Wien," "Dr. Niehans Zellular-Therapie Siccazell * * * Nebenniere tot. mas. (Kalb) (or other ingredients) * * * Suspensionsmittel Rhein-Chemie Heidelberg Vertrieb: Pharmackon AG Zurich" or "Dr. Niehans Siccazell * * * Dunndarm (or other ingredients) * * * Ringerlosung Rhein-Chemie Heidelberg Vertrieb: Pharmackon AG Zurich," "Dr. Niehans Zellular-Therapie Nebenniere tot. mas. (Kalb) (or other ingredients)," or "Siccacell Eierstock total * * * Rhein-Chemie Abt. Organtherapie Heidelberg."

LIBELED: On or about 1–3–64, S. Dist. N.Y.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of a new-drug application was effective with respect to the articles and they were not exempt since they did not comply with regulations governing new drugs for investigational use.

DISPOSITION: 2–11–64. Default—destruction.

8084. Coftoc Cough Medicine. (F.D.C. No. 47384. S. No. 39–913 T.)

QUANTITY: 30 cases, each containing 72 4-oz. btls., at New York, N.Y.

SHIPPED: 1–16–62, from Roselle, N.J., by L. M. Research Products, Inc.

LABEL IN PART: (Btl.) "Hudson Coftoc Cough Medicine Non-Narcotic Antitussive Sedative Expectorant * * * Hudson Vitamin Products, Inc., N.Y., N.Y. * * * Each Teaspoonful (5 cc.) contains Dextromethorphan Hydrobromide 10 mg. * * * Dosage."

RESULTS OF INVESTIGATION: Analysis showed that the article contained essentially the labeled amount of dextromethorphan hydrobromide.

LIBELED: 3–19–62, S. Dist. N.Y.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 4–12–62. Default—destruction.

8085. Abaphage tablets. (F.D.C. No. 48999. S. Nos. 62–745/6 V.)

QUANTITY: 5 ctns., each containing 12 100-tablet btls. and 13 1,000-tablet btls., of 10-mg. tablets, and 5 ctns., each containing 12 100-tablet btls. and 8 1,000-tablet btls., of 20-mg. tablets, at Lomita, Calif.

SHIPPED: Between 4–18–62 and 5–21–63, from Brooklyn, N.Y., by Rexar Pharmacal Corp.

LABEL IN PART: (Btl.) "ABAPHAGE * * * Dose: * * * Caution * * * Quadrigon Pharmacal, Inc. Los Angeles Each Tablet Contains: Methamphetamine Saccharate 2.5 mg. [or "5 mg."] Methamphetamine Hydrochloride 2.5 mg. [or "5 mg."] Amphetamine Sulfate 2.5 mg. [or "5 mg."] Dextro Amphetamine Sulfate 2.5 mg. [or "5 mg."]."

ACCOMPANYING LABELING: Bottle inserts entitled "Abaphage Effects * * * No Strict Starvation Diets Are Necessary * * * Contraindications * * * Feb. 63."

LIBELED: 6–7–63, S. Dist. Calif.; libel amended 6–24–63.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 4–15–64. Default—destruction.

8086. Apcol capsules and Coronate-45 Time capsules. (F.D.C. No. 49494. S. Nos. 3–034 X, 3–037 X.)

QUANTITY: 2 drums, containing a total of 80,000 capsules, and a number of btls., containing a total of 17,000 capsules, of *Apcol capsules;* and 296 60-capsule btls. of *Coronate-45 Time capsules*, at Princeton, W. Va.

SHIPPED: (*Apcol capsules*) 9–10–63, from Greenville, S.C., by Libby, Edwards & Brown, Inc.; and *Coronate-45 Time capsules*) 10–23–62, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Drum) "Table Rock Laboratories, Greenville, S.C. * * * Manufactured for Milan Pharmaceuticals, Inc. * * * Apcol Capsules P. F. * * * Each capsule contains 21 mg. of (L-isomer) 1-phenyl-2-Aminopropane Succinate Caution," and (btl.) "Coronate-45 Manufactured for Milan Pharmaceuticals, Inc. Princeton, West Virginia. Contraindication * * * Each Time Capsule Contains: Pentaerythritol Tetranitrate 45 mg. Indication * * * Action * * * Dosage."

RESULTS OF INVESTIGATION: The articles had been shipped in bulk drums and had been repacked in part, by the dealer, into bottles.

LIBELED: 11–4–63, S. Dist. W. Va.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was in effect with respect to such drugs.

DISPOSITION: 3–4–64. Default—destruction.

8087. **Surgident's Predlon Kit (drug and device).** (F.D.C. No. 50533. S. No. 61–339 A.)

QUANTITY: 37 ctns. of 6 pkgs each, at Los Angeles, Calif.

SHIPPED: 9–17–64, from Bothell, Wash., by Vermilye-Bell.

LABEL IN PART: (Pkg.) "Surgident's Predlon Kit Dental Suspension–Topical—Distributed by Surgident, Ltd., Los Angeles, Calif * * * Contains 1–6 cc. Predlon Suspension 1–1 cc. Syringe, 2–19 Ga. Needles, 1 Pkg. Asbestos Discs—Each cc. Predlon Suspension Contains 5 Mg. Prednisolone Acetate, 100 Mg. Sulfacetamide Sodium."

ACCOMPANYING LABELING: Package inserts entitled "Surgident's Predlon."

LIBELED: 10–2–64, S. Dist. Calif.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 12–3–64. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

8088. **Multidisk Sensitivity Discs.** (F.D.C. No. 49074. S. Nos. 89–804/5 T.)

QUANTITY: 32 jars of 50 discs each, at New Hyde Park, N.Y.

SHIPPED: 9–4–62, from Chicago Heights, Ill., by Consolidated Laboratories, Inc.

LABEL IN PART: (Jar) "Multidisk Sensitivity Discs * * * Mfg. by Consolidated Laboratories, Inc., Chicago Heights, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that several of the antibiotics in each lot contained less than the declared potency.

LIBELED: 6–17–63, E. Dist. N.Y.; libel amended 3–11–64.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(l)—the article was represented as a drug composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: Consolidated Laboratories, Inc., appeared and answered the libel and amended libel. Thereafter, on 9–30–64, the claimant withdrew its answers to the libel and amended libel. A default decree of condemnation ordering destruction of the goods was entered on 12–4–64.

8089. **Bro-Parin-H.** (F.D.C. No. 50087. S. No. 97–565 A.)

QUANTITY: 160 ctns., each containing 12 5–cc. btls., at San Francisco, Calif., in possession of Broemmel Pharmaceuticals.

SHIPPED: The article was manufactured by the dealer, in part, from polymyxin B sulfate and neomycin sulfate shipped 10–21–63 and 3–13–62, from Princeton, N.J.

LABEL IN PART: (Btl.) "Prod. No. 129 sterile otic suspension * * * Bro-Parin-H active ingredients: polymyxin B sulfate 50,000 U/cc neomycin (as sulfate) 10.0 mg/cc * * * Broemmel Pharmaceuticals, S.F."

LIBELED: 5–13–64, N. Dist. Calif.

CHARGE: 502(l)—while held for sale, the article purported to be composed of antibiotics and it was not from a batch with respect to which a certificate or release had been issued, and the article was not exempt from such requirement.

DISPOSITION: 11–19–64. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8090. Dextro-amphetamine sulfate powder, desoxyephedrine hydrochloride powder, and cantharidin powder. (F.D.C. No. 50168. S. Nos. 31–649 V, 31–651 V, 31–656 V, 32–756 V.)

INFORMATION FILED: 7–17–64, S. Dist. Calif., against Calbiochem, a corporation, Los Angeles, Calif.

ALLEGED VIOLATION: Between 1–21–63 and 3–1–63, while quantities of *dextro-amphetamine sulfate powder* and quantities of *desoxyephedrine hydrochloride powder* were being held for sale after shipment in interstate commerce, the defendant caused *dextro-amphetamine sulfate powder* to be dispensed twice and the *desoxyephedrine hydrochloride powder* to be dispensed once, without a prescription, which acts resulted in the drugs being misbranded.

In addition, on 3–8–63, the defendant caused a quantity or misbranded *cantharidin powder* to be introduced and delivered for introduction into interstate commerce, at Los Angeles, Calif., for delivery to Phoenix, Ariz.

LABEL IN PART: (Vial) "Cantharidin, C grade * * * Not For Drug Use * * * Poison Avoid Skin Contact California Corporation For Biochemical Research Los Angeles."

CHARGE: *Dextro-amphetamine sulfate powder* and *desoxyephedrine hydrochloride powder*, 503(b)(1)—while held for sale; the articles were drugs within the meaning of 503(b)(1)(B) and were dispensed without a prescription.

Cantharidin powder, 503(b)(4)—when shipped, the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 10–13–64. $800 fine.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

8091. Peyote buttons. (F.D.C. No. 45962. S. Nos. 36–294 R, 36–296 R, 36–298 R, 36–300 R, 59–981 R.)

INDICTMENT RETURNED: 9–10–62, S. Dist. Tex., against Smith's Cactus Ranch, a partnership, Laredo, Tex., and George V. Smith, a partner.

ALLEGED SHIPMENTS: Between 6–7–60 and 9–19–60, from Laredo, Tex., to Carlisle, Harrisburg, and New Cumberland, Pa., and New Orleans, La.

CHARGE: All the alleged shipments, 502(b)(2)—when shipped, the article failed to bear a label containing an accurate statement of the quantity of contents; 502(d)—the article contained a quantity of the narcotic or hypnotic substance,

*See also No. 8090.

peyote, and its label failed to bear the name and quantity or proportion of such substance and, in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; and 503(b)(4)—the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Alleged shipments to Carlisle, Pa., and New Orleans, La., 502(b)(1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

PLEA: Not guilty.

DISPOSITION: On 2–4–63, the case came on for trial by the court, and, upon conclusion of the trial, the court found the defendants not guilty.

8092. Dipyrone injection. (F.D.C. No. 50446. S. No. 36–061 A.)

QUANTITY: 170 30-cc. vials at Dayton, Ohio.

SHIPPED: 7–25–63 and 9–25–63, from Decatur, Ill., by Taylor Pharmacal.

LABEL IN PART: (Vial) "Dipyrone 50% W/V Each cc. contains Dipyrone 0.5 Gram in water for injection * * * Distributed by Moffet Laboratories, Inc. Dayton, Ohio * * * Indications: Analgesic antipyretic and antirheumatic."

ACCOMPANYING LABELING: Leaflets entitled "Dipyrone * * * Uses and Administration."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 86 percent of the declared amount of dipyrone.

LIBELED: 8–14–64, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes; 503(b)(4)—the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–28–64. Default—destruction.

8093. Effervescing Midy Granules. (F.D.C. No. 48604. S. No. 39–204 V.)

QUANTITY: 250 2½-oz. cans at Hicksville (Long Island), N.Y.

SHIPPED: 4–18–62, from Paris, France, by Laboratoires Midy.

LABEL IN PART: (Can) "Effervescing Midy Granules An Effervescent Alkalizing Mixture Contains * * * Piperazine * * * Made In France Laboratoires Midy * * * Paris-France R. Midy, Docteur en Pharmacie Distributed by E. Fougera and Co. Inc. Hicksville, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 3.46 percent piperazine.

LIBELED: 1–22–63, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements that the article was a simple alkalizing preparation, which statements were false and misleading as applied to an anthelmintic preparation; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and

it was not exempt from such requirement; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: On 2–13–63, Laboratoires Midy, Paris, France, filed a claim to the article, and filed an answer denying that the article was misbranded. On 1–5–64, the Government served written interrogatories on the claimant.

On 2–20–64, in view of the claimant's failure to respond to the interrogatories, the Government moved for an order dismissing the claimant's answer and granting judgment to the Government for the claimant's failure to respond to the written interrogatories.

On 3–23–64, the court granted the Government the relief it had requested, unless the claimant, on or before 4–23–64, served and filed answers to the written interrogatories.

On 5–15–64, a default decree of condemnation and destruction was entered.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

8094. Calcium tablets. (F.D.C. No. 47305. S. No. 94–482 A.)

INFORMATION FILED: 3–9–62, E. Dist. Mich., against William L. Abt, Detroit, Mich.

SHIPPED: 5–18–61, from Buffalo, N.Y., to Detroit, Mich.

LABEL IN PART: (Btl.) "90 Tablets Calcium From Egg Shells: 3 Tablets Contains * * * Abtco Distributors, Los Angeles, California."

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the diseases, symptoms, conditions, and purposes for which it was intended, namely, improper bone growth, improper functioning of bone marrow, bones, thyroid, and parathyroid, improper pH of the blood, longevity, and lack of strength and firmness of the arteries.

PLEA: Guilty.

DISPOSITION: 12–21–62. 1 year in prison suspended, $1,000 fine, and probation for 2 years.

8095. Anafac capsules. (F.D.C. No. 49607. S. No. 20–387 X.)

QUANTITY: 406 100-capsule btls. and 9 1,000-capsule btls., at Austin, Tex., in possession of Pharmafac, Inc.

SHIPPED: 5–22–63, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Anafac Analgesic-Antipyretic * * * Each capsule contains: Methampyrone (Dipyrone) 300 mg. N-Acetyl-P-Aminophenol 100 mg. Adiphenine Hydrochloride 10 mg. Phenyltoloxamine Citrate 20 mg. CAUTION: * * * Manufactured for Pharmafac Austin, Texas."

RESULTS OF INVESTIGATION: The article had been repacked and labeled as above. by the dealer, from bulk lots shipped as above.

LIBELED: 1–30–64, W. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since it was a prescription drug which was a new drug subject to 505,

*See also Nos. 8081, 8090, 8092, 8093.

and its labeling bearing the information for use of the article as prescribed by regulations was not the labeling authorized by an effective new-drug application.

DISPOSITION: 5–4–64. Default—destruction.

8096. Dextro-amphetamine sulfate capsules. (F.D.C. No. 49659. S. No. 29–950 X.)

QUANTITY: 2 pkgs. of 50,000 capsules each, at Houston, Tex.

SHIPPED: 12–12–63, from Harrington Park, N.J., by Norval Pharmacal Co.

LABEL IN PART: (Pkg.) "Dextro Amphetamine Sulfate U.S.P. 15 mg. * * * Disintegrating Capsules."

RESULTS OF INVESTIGATION: The article was consigned for delivery to Tex Palmer, t/a Crest Laboratories, Houston, Tex. Mr. Palmer was not licensed under Texas State law to deal in prescription drugs.

LIBELED: 12–24–63, S. Dist. Tex.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement.

DISPOSITION: 1–27–64. Default—destruction.

8097. Amphetamine tablets and capsules. (F.D.C. No. 49644. S. Nos. 2–394/8 A.)

QUANTITY: Approximately 100,000 tablets and capsules in various containers, at Darien, Ga., in possession of M. Eugene King, a truck stop operator.

SHIPPED: On unknown dates prior to 12–16–63, from outside the State of Georgia.

LIBELED: On or about 12–11–63, S. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from that requirement, since it was a prescription drug in the possession of a person who was not regularly engaged in the manufacture, transportation, storage, or distribution of prescription drugs and it would not be used nor dispensed in accordance with 503(b).

DISPOSITION: 6–12–64. Default—delivered to the Food and Drug Administration.

8098. Amphetamine-containing drugs. (F.D.C. No. 50074. S. Nos. 56–605/7 A.)

QUANTITY: 30,000 tablets and capsules at Des Moines, Iowa, in possession of Dean G. Hume, D.O.

SHIPPED: On various dates prior to 5–12–64, outside the State of Iowa.

LIBELED: 5–12–64, S. Dist. Iowa.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since they were prescription drugs which would not be used nor dispensed by the practitioner in the course of his professional practice

DISPOSITION: 6–27–64. Default—destruction.

8099. Amphetamine- and barbiturate-containing drugs. (F.D.C. No. 50098. S. Nos. 56–608/13 A.)

QUANTITY: 5,000 amphetamine-containing drugs and approximately 1,000 barbiturate-containing drugs at Des Moines, Iowa, in possession of John Birden, t/a Iowa Upholstery Co.

SHIPPED: Prior to 5–18–64, from outside the State of Iowa.

LIBELED: 5–25–64, S. Dist. Iowa.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: 6–26–64. Default—destruction.

8100. Amphetamine-containing and other prescription drugs (3 seizure actions). F.D.C. Nos. 49428, 49514, 49657. S. Nos. 29–698/9 X; 62–008 X, 62–015/16 X; 62–017 X.)

QUANTITY: 50,000 *amphetamine-containing drugs*, 15,000 *desoxyephedrine hydrochloride tablets*, 200 *Darvon Compound capsules*, 1,000 *methyltestosterone tablets*, and 250 *Butazolidin tablets*, at Omaha, Nebr., in possession of Harry G. Williams.

SHIPPED: On unknown dates, from outside the State of Nebraska.

LIBELED: 10–28–63, 10–31–63, and 11–6–63, Dist. Nebr.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since they were in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since they were not to be dispensed upon prescription.

DISPOSITION: 12–9–63, 12–9–63, 12–4–63. Default—condemned and ordered held by the marshal as evidence.

8101. Desoxyephedrine hydrochloride tablets. (F.D.C. No. 49800. S. No. 72–105 A.)

QUANTITY: 1 box of 65,000 tablets at Lake Charles, La.

SHIPPED: 2–3–64, from Harrington Park, N.J., by Norval Pharmacal.

LABEL IN PART: (Box) "Dl-Desoxyephedrine HCl Each tablet contains Dl-Desoxyephedrine HCl 7.5 mg. Caution: * * * Mfd. for Norval Pharmacal Harrington Park, N.J."

LIBELED: 2–12–64, W. Dist. La.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since it was shipped to a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs.

DISPOSITION: 3–13–64. Default—destruction.

8102. Multiglands injection. (F.D.C. No. 49957. S. No. 79–725 A.)

QUANTITY: 115 30–cc. vials at Newark, N.J.

SHIPPED: 10–11–63, from Philadelphia, Pa., by Vitamix Pharmaceuticals, Inc.

LABEL IN PART: (Vial and ctn.) "Multiple Dose Vial Multiglands (Pluri-gland Extract) Intramuscular Only Caution: * * * Vitamix Pharmaceuticals Incorporated Philadelphia, Penna. Each 2 cc. represents the water soluble extraction of dried glands derived from Suprarenal Cortex, fresh gland * * * Thyroid, fr. gl. * * * Pituitary Anterior, fresh gland * * * Pituitary Posterior, fresh gland * * * Ovarian Substance, fresh gland * * * Thymus, fr. gl. * * * Lymphatic, fr. gl. * * * Dose * * * Indications."

LIBELED: 4–2–64, Dist. N.J.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 5–13–64. Default—destruction.

8103. Various drugs. (F.D.C. No. 49565. S. Nos. 45–870/4 X.)

QUANTITY: 21,000 tablets and/or capsules of *barbiturate drugs*, 5,500 tablets and/or capsules of *meprobamate drugs*, and 6,500 tablets and/or capsules of *amphetamine drugs*, at Advance, Mo., in possession of Dr. E. C. Masters, Masters & Masters Clinic.

SHIPPED: Prior to and including 12–18–63, from Brooklyn, N.Y., Bronx, N.Y., Indianapolis, Ind., Chicago, Ill., Philadelphia, Pa., and elsewhere outside the State of Missouri, by unknown drug handlers.

LIBELED: On or about 12–19–63, E. Dist. Mo.

CHARGE: 502(f)—while held for sale, the labeling of the articles failed to bear (1) adequate directions for use, and (2) such adequate warnings against use as are necessary for the protection of users, and the articles were not exempt from such requirements.

DISPOSITION: 5–5–64. Default—50 capsules and/or tablets from each container delivered to the Food and Drug Administration; remainder destroyed.

8104. Various prescription drugs. (F.D.C. No. 49888. S. Nos. 12–535/8 X, 87–001/19 X.)

QUANTITY: 360 segregated lots, such as 14 50-tablet btls., 2 unlabeled 50-capsule btls., 22 50-tablet btls., and 12 6-ampul boxes, at Chicago, Ill.

SHIPPED: Prior to 6–24–63, from outside the State of Illinois.

RESULTS OF INVESTIGATION: The articles were subject to water damage in June 1963, at Oaklawn, Ill. These drugs had been reclaimed by a salvage dealer (Western Salvage & Appraisal Co., Chicago, Ill.) who, after purportedly reconditioning the goods, sold them to the dealer. Examination showed that the goods consisted of stain-damaged, moldy, and rusted containers and packaging, incompletely labeled or completely unlabeled containers, and incorrectly identified drugs and drugs that were not positively identifiable.

LIBELED: 2–20–64, N. Dist. Ill.

CHARGE: 501(a)(2)(A)—while held for sale, the articles were held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: 3–12–64. Consent—claimed by Sanco Drug Co., Chicago, Ill. Segregated; approximately 90 percent of the drugs destroyed.

8105. Various prescription drugs. (F.D.C. No. 49950. S. Nos. 6–130/42 A, 9–202 A.)

QUANTITY: Several thousand tablets and capsules of *barbiturate-containing drugs, amphetamine-containing drugs, meprobamate-containing drugs*, and *methyltestosterone tablets*, at Lindside, W. Va., in possession of Thomas G. Matney, M.D.

SHIPPED: Prior to 3–30–64, from outside the State of West Virginia.

LIBELED: On or about 4–1–64, S. Dist. W. Va.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from such requirement, since they were prescription drugs which would not be used or dispensed by a licensed practitioner in the course of his professional practice in accordance with 503(b).

DISPOSITION: 5–11–64. Default—destruction.

8106. Angibarb capsules and Angitol capsules. (F.D.C. No. 50065. S. Nos. 46–657/8 X.)

QUANTITY: 58 100-capsule btls., 1 300-capsule btl., and 40 3-capsule btls., of *Angibarb*, and 101 100-capsule btls., 6 1,000-capsule btls., and 52 4-capsule btls., of *Angitol*, at Little Rock, Ark., in possession of Gateway Laboratories, Inc.

SHIPPED: 5–6–60 and 5–11–60, from Memphis, Tenn.

LABEL IN PART: (Btl.) "Angibarb [or "Angitol"] 80 TD each capsule contains: Pentaerythritol Tetranitrate 80 mg. * * * Manufactured for: Gateway Laboratories, Inc. Little Rock, Arkansas."

RESULTS OF INVESTIGATION: The articles were shipped in bulk and repacked and labeled as above, by the dealer.

LIBELED: 4–29–64, E. Dist. Ark.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement, since they were prescription drugs which were new drugs subject to 505 and their labeling was not labeling authorized by approved new-drug applications.

DISPOSITION: 6–18–64. Default—destruction.

8107. Auto-Electronic Radioclast Model 20 device and Radioclast Model RR 20 device. (F.D.C. No. 49776. S. Nos. 18–529/30 A.)

QUANTITY: 1 *Auto-Electronic Radioclast Model 20 device* and 1 *Radioclast Model RR 20 device*, at Cambridge Springs, Pa.

SHIPPED: Between 1–31–58 and 1–31–60, from Tiffin, Ohio.

RESULTS OF INVESTIGATION: Examination indicated that the *Auto-Electronic Radioclast Model 20* was intended for diagnostic use and was a wood cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of three dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease condition present, and additional dials determined the intensity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determine the location of the disease in the body.

The *Radioclast Model RR 20* was similar in design and construction to the above-described device, except that it was equipped with electrodes for treatment purposes.

LIBELED: 2–11–64, W. Dist. Pa.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and adequate directions for use cannot be written since the articles are worthless for any medical purposes.

DISPOSITION: 9–23–64. Default—delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

8108. **Arsanate tablets.** (F.D.C. No. 47804. S. No. 29–506 T.)

QUANTITY: 60 100-tablet btls. at Kansas City, Mo.

SHIPPED: 9–12–61 and 3–23–62, from Lincoln, Nebr., by Norden Laboratories, Inc.

LABEL IN PART: "Arsanate Tablets (5 Gallon Size) For Use In Drinking Water For Swine As An Aid In Treament of Swine Dysentery. Each Tablet Contains: Sodium Arsanilate Equivalent to 11.0 Grs. Elemental Arsenic or 14.5 Grs. Arsenic Trioxide—Directions: * * * Professional Use By Veterinarians Norden Laboratories, Lincoln, Nebraska."

LIBELED: On or about 7–23–62, W. Dist. Mo.

CHARGE: 502(f)(2)—when shipped, the labeling of the article failed to bear a warning to discontinue use of the drug at least five days before slaughtering the animal for food, to eliminate the drug from the food.

DISPOSITION: 12–5–62. Default—destruction.

8109. **Clay.** (F.D.C. No. 49990. S. No. 44–117 A.)

QUANTITY: 54 bags at Eaton, Colo.

SHIPPED: 1–22–64, from El Centro, Calif., by Basin Bean Co.

LABEL IN PART: (Apparently reused bags) "Flour * * * 100 Lbs. Net."

RESULTS OF INVESTIGATION: Examination showed the article to be a light brown powdered substance having the consistency and appearance of fine dirt. The article was intended for sale as a mineral supplement for control of scours in cattle and sheep.

LIBELED: 4–23–64, Dist. Colo.

CHARGE: 502(a)—when shipped, the label statement "Flour" was false and misleading as applied to a product which was not flour, and which was intended for drug use; 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)(A)(i)—the article failed to bear the established name of the drug; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from that requirement.

DISPOSITION: 6–17–64. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF INSANITARY CONDITIONS*

8110. **Soda mint tablets and phenylephrine hydrochloride and prophenpyridamine maleate tablets.** (F.D.C. No. 47103. S. Nos. 30–437 T, 43–006 T, 44–603 T, 45–787 T.)

INFORMATION FILED: 11–8–62, E. Dist. N.Y., against Nysco Laboratories, Inc., Long Island City, N.Y.

ALLEGED VIOLATIONS: Between 3–3–61 and 3–30–62, packages, and a drum, of adulterated *soda mint tablets*, and drums of adulterated *phenylephrine hydro-*

*See also No. 8104.

chloride and prophenpyridamine maleate tablets, were shipped from Long Island City, N.Y., to San Francisco, Calif., Springfield, Mo., and Montclair, N.J.

The information alleged violations also with respect to adulterated foods, as reported in notices of judgment on foods.

LABEL IN PART: (Drum of *soda mint tablets*) "NYSCO Laboratories, Inc. * * * Soda Mint Tablets * * * 5 grains * * * Each Tablet contains Sodium Bicarbonate 5 grains Oil of Peppermint."

CHARGE: 501(a)(2)—when shipped, the articles had been prepared under insanitary conditions whereby they may have been rendered injurious to health; 501(c)—the purity and quality of the articles fell below that which they were purported and represented to possess since they contained diethylstilbestrol; and 501(d)(2)—diethylstilbestrol had been substituted in part for sodium bicarbonate in the *soda mint tablets* and, in part, for the mixture of phenylephrine hydrochloride and propenpyridamine maleate in the other tablets.

PLEA: Guilty.

DISPOSITION: 12–5–63. $1,200 fine on the counts involving drugs; $2,000 total fine.

DRUG WITHOUT ASSURANCE OF CURRENT GOOD MANUFACTURING PRACTICE

8111. **Mineral oil (3 seizure actions).** (F.D.C. No. 50138. S. Nos. 56–243 A, 56–986 A, 57–192 A.)

QUANTITY: 101 cases, each containing 12 1-pt. btls., at Omaha, Nebr.; 140 cases, each containing 12 1-pt. btls., at South Sioux City, Nebr.; and 103 qt. btls., at Lincoln, Nebr.

SHIPPED: Between 2–24–64 and 3–26–64, from Seagoville, Tex., by Dixie Laboratories.

LABEL IN PART: (Btl.) "Hospital Brand Heavy Mineral Oil * * * Refined For Internal Use * * * Contents * * * Distributed by Dixie Laboratories Seagoville, Texas."

RESULTS OF INVESTIGATION: Examination showed that the article contained isopropanol. Investigation showed that isopropanol and mineral oil had been unloaded through the same discharge pipe at the plant of Dixie Laboratories. Bottles from known isopropanol-contaminated stock also had been refilled, without washing, for distribution.

LIBELED: 5–22–64, Dist. Nebr.

CHARGE: 501(a)(2)(B)—when shipped, the methods used in, and the facilities or controls used for, the manufacture, processing, packing, and holding of the article did not conform to, and were not operated and administered in conformity with, current good manufacturing practice; 501(b)—the quality and purity of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Refined for Internal Use" was false and misleading, since it was not suitable for internal use because of contamination with isopropanol.

DISPOSITION: 7–7–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

8112. **Nitroglycerin and phenobarbital tablets.** (F.D.C. No. 50135. S. No. 56–962 A.)

QUANTITY: 2 drums containing a total of approximately 100,000 tablets at Parsons, Kans.

SHIPPED: 11–1–63, from Cedar Rapids, Iowa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained from 34 percent to 57 percent of the declared amount of nitroglycerin.

LIBELED: On or about 6–4–64, Dist. Kans.

CHARGE: 502(a)—while held for sale, the label statement "Each Tablet Contains Nitroglycerine 1/100 gr." was false and misleading as applied to a product containing less than the declared amount of this ingredient; and 501(c)—the strength of the article differed from that which it was represented to possess.

DISPOSITION: 7–14–64. Default—destruction.

8113. **Chlorprophenpyridamine maleate timed disintegration capsules.** (F.D.C. No. 47579. S. No. 39–385 T.)

QUANTITY: 24 1,000-capsule cans at Brooklyn, N.Y.

SHIPPED: 10–30–61, from Hoboken, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Can) "Timed Disintegration Capsules Chlorprophenpyridamine Maleate U.S.P. Each Capsule Contains: Chlorprophenpyridamine Maleate 8 mg. (Warning: May be habit forming) * * * Distributed by Rugby Laboratories, Inc., Brooklyn, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 84.7 percent of the declared amount of chlorprophenpyridamine maleate.

LIBELED: 5–10–62, E. Dist. N.Y.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Each Capsule Contains: Chlorprophenpyridamine Maleate 8 mg." was false and misleading.

DISPOSITION: 6–20–62. Default—destruction.

8114. **Tranquilizer tablets and vitamin K tablets.** (F.D.C. No. 49981. S. Nos. 84–009/10 A.)

QUANTITY: 27 1,000-tablet btls. and 274 50-tablet btls. of *tranquilizer tablets*, and 62 1,000-tablet btls. of *vitamin K tablets*, at Santurce, P.R.

SHIPPED: On or about 4–13–59, from Katonah, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the *tranquilizer tablets*, represented as containing mannitol hexanitrate 30 mg., rutin 30 mg., and rauwolfia serpentina (whole root) 50 mg., contained no rauwolfia serpentina; that their content of mannitol hexanitrate varied from 83.5 percent to 95.0 percent; and that their content of rutin varied from 85.3 percent to 93.7 percent.

Analysis showed that the article, *vitamin K tablets*, represented as containing

*See also Nos. 8088, 8092, 8110, 8111.

5 milligrams of vitamin K (menadione), contained between approximately 83.3 percent and 77.8 percent of the declared amount of menadione.

LIBELED: 4–28–64, Dist. P.R.

CHARGE: *Tranquilizer tablets*, 501(c)—while held for sale, the article differed in strength from that which it was purported to possess; and 502(a)—the label statement "Each Tablet Contains: Mannitol hexanitrate 30 mg.; Rutin 30 mg.; Rauwolfia Serpentina (whole root) 50 mg." was false and misleading since the article contained less than the declared amounts of those ingredients.

Vitamin K tablets, 501(b)—while held for sale, the article purported to be and was represented as a drug, Menadione, the name of which was recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statements "Each tablet contains 5 mg. Menadione USP" and "Each Tablet contains 5 mg. Vitamin K" were false and misleading, since the article contained less than the declared amount of this ingredient.

DISPOSITION: 6–25–64. Default—destruction.

8115. Chorionic gonadotropin. (F.D.C. No. 49575. S. Nos. 58–265/6 X.)

QUANTITY: 463 5,000-I.U. vials and 340 10,000-I.U. vials, at Los Angeles, Calif., in possession of Maurry Biological Co.

SHIPPED: The article was manufactured by the dealer, Maurry Biological Co., in part from ingredients, namely, chorionic gonadotropin powder, shipped 7–7–62, from Little Falls, N.J.

LABEL IN PART: (Vial) "Lyophilized Chorionic Gonadotropin * * * Caution: Federal Law Prohibits * * * For Intramuscular Injection * * * Manufactured by Maurry Biological Co. Los Angeles, Calif., U.S.A.," and "Lyophilized Chorionic Gonadotropin."

RESULTS OF INVESTIGATION: Analysis showed that the article had a potency of less than 25 percent of the label claim.

LIBELED: 12–26–63, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statements "5,000 I.U." and "10,000 I.U." were false and misleading.

DISPOSITION: 6–18–64. Default—destruction.

8116. Digitalis tablets. (F.D.C. No. 50038. S. No. 84–014 A.)

QUANTITY: 164 100-tablet btls. and 5 1,000-tablet btls. at Santurce, P.R.

SHIPPED: Prior to 1959, from Katonah, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 34.3 percent of the declared potency of digitalis per tablet.

LIBELED: 4–27–64, Dist. P.R.

CHARGE: 501(b)—while held for sale, the strength of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Digitalis 1½ grain tablets" was false and misleading.

DISPOSITION: 6–25–64. Default—destruction.

8117. Rubber prophylactics. (F.D.C. No. 48841. S. Nos. 55–582/5 V.)

QUANTITY: 132 ctns. of 1-gross units each, and 700 gross units in bulk ctns., at Kansas City, Mo.

SHIPPED: Between 2–14–63 and 2–25–63, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Ctn.) "Gold Circle Coin Type * * * Micro-Thin Transparent Prophylactics * * * Manufactured by Circle Rubber Corp. Newark, N.J. Sold For the Prevention of Disease Only"; (foil wrapper) "Circle Rubber Corp. Newark, N.J. Latex Transparent Prophylactic Micro Thin"; and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination of the articles showed that from 1.35 to 6 percent of the units in the lots tested were defective in that they contained holes.

LIBELED: 4–8–63, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they were purported to possess; and 502(a)—the label statements "Sold For Prevention of Disease Only" were false and misleading.

DISPOSITION: 5–20–63. Consent—claimed by Circle Rubber Corp. and segregated; 50 lbs. destroyed.

8118. **Cotton swabs.** (F.D.C. No. 49940. S. No. 78–536 A.)

QUANTITY: 1,080 pkgs., each containing 4 90-swab boxes, at New York, N.Y.

SHIPPED: 2–10–64, from Jersey City, N.J., by Twin-Ets Manufacturing Co., Inc.

LABEL IN PART: (Box) "Macy's Double Tipped Cotton Swabs Sterilized Before Wrapping 90 Swabs (180 Tips) * * * 100% Sterile."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable micro-organisms.

LIBELED: On or about 3–20–64, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; 502(a)—the label statements "Sterilized Before Wrapping" and "100% Sterile" were false and misleading; and 502(b)(1)—the label failed to bear the address of the distributor and the qualifying phrase "distributed by" or other similar phrase which expressed the facts.

DISPOSITION: 5–12–64. Default—destruction.

DRUGS FOR VETERINARY USE

8119. **Medicated turkey feed.** (F.D.C. No. 49303. S. No. 46–111 X.)

QUANTITY: 50 50-lb. bags at Weldon, Ill.

SHIPPED: 6–21–63, from Clinton, Iowa, by Pillsbury Co.

LABEL IN PART: (Tag) "Pillsbury's Best No-mix Turkey Concentrate medicated for the prevention of blackhead in Turkey flocks when fed as directed on the label. Active drug ingredient: 4-Nitrophenylarsonic acid .05% * * * Manufactured by the Pillsbury Company Feed Division * * * Minneapolis, Minnesota Directions for feeding this concentrate is to be fed free choice with an equal amount of grain."

RESULTS OF INVESTIGATION: Analysis showed that the turkey concentrate contained approximately 57 percent of the declared amount of 4-nitrophenylarsonic acid.

LIBELED: 9–9–63, S. Dist. Ill.; libel amended 1–20–64.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "4-Nitrophenylarsonic acid .05%" was false and misleading.

DISPOSITION: 2–25–64. Default—destruction.

8120. Medicated feed. (F.D.C. No. 50222. S. No. 30–241 A.)

QUANTITY: 50 100-lb. bags at Louisville, Ky.

SHIPPED: 3–26–64 and 4–17–64, from Cincinnati, Ohio, by Cooperative Mills, Inc.

LABEL IN PART: (Tag) "Cooperative Mills Inc. * * * Starting & Growing Mash Medicated (A) * * * Amprolium .006% * * * Cooperative Mills, Inc. * * * Cincinnati, Ohio."

RESULTS OF INVESTIGATION: Anaylsis showed that the article contained approximately 76 percent of the declared amount of amprolium.

LIBELED: 6–8–64, W. Dist. Ky.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Amprolium .006%" was false and misleading.

DISPOSITION: 7–21–64. Consent—delivered to a public institution for use as animal feed.

8121. Medicated feed. (F.D.C. No. 48686. S. Nos. 34–353 V, 35–728 V.)

QUANTITY: 55 50-lb. bags at Superior, Wis.

SHIPPED: 12–12–61 and 5–18–62, from St. Paul, Minn.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 60 percent of the declared amount of diethylstilbestrol.

LIBELED: 1–28–63, W. Dist. Wis.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement (tag) "Diethylstilbestrol .00227%" was false and misleading as applied to an article containing less than the declared amount of this ingredient.

DISPOSITION: 3–26–63. Default—destruction.

8122. Kasco Mom 'N' Pup Food. (F.D.C. No. 49788. S. Nos. 6–838/9 X.)

QUANTITY: 35 bags, each containing 2 25-lb. bags, and 42 bags, each containing 5 10-lb. bags, at St. Albans, Vt.

SHIPPED: 8–8–63 and 9–10–63, from East St. Louis, Ill., by Corn Products Co.

LABEL IN PART: (Bag) "Kasco Mom 'N' Pup Food Medicated For Prevention and Elimination * * * Active Drug Ingredient: Diethylcarbamazine 0.0066% * * * Best Foods Div. Corn Products Co. New York 22, N.Y."

RESULTS OF INVESTIGATION: The article contained approximately 65 percent (35-bag lot) and 68 percent (42-bag lot) of the declared amount of diethylcarbamazine.

LIBELED: On or about 2–17–64, Dist. Vt.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Active Drug Ingredient: Diethylcarbamazine 0.0066%" was false and misleading as applied to an article containing less than the declared amount of this ingredient.

DISPOSITION: 5–14–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

8123. Imitation Dexamyl Spansule capsules. (F.D.C. No. 49525. S. No. 7–069 X.)

QUANTITY: 9 250-capsule btls. at Malden, Mass.

SHIPPED: 9–5–63, from Chicago, Ill., by Biddle Purchasing Co.

RESULTS OF INVESTIGATION: Analysis showed that the article contained amobarbital and dextro-amphetamine sulfate, and that it was not the product of Smith, Kline & French Laboratories.

LIBELED: 11–20–63, Dist. Mass.

CHARGE: 502(a)—when shipped, the name of the article, "Dexamyl," was false and misleading as applied to a product which was an imitation of "Dexamyl"; 502(i)(2)—the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 7–21–64. Default—destruction.

8124. Appetite Depressant tablets. (F.D.C. No. 50133. S. Nos. 51–365/6 A.)

QUANTITY: A number of drums containing approximately 2,620,200 tablets, and undetermined quantities of btls. of the article, at Cleveland, Ohio, in possession of Reese Chemical Co.

SHIPPED: The article was manufactured by Strong, Cobb, Arner, Inc., Cleveland, Ohio, in part from phelylpropanolamine hydrochloride which was shipped from the State of New York between 11–1–63 and 2–20–64, and the finished tablets were subsequently delivered to the dealer.

LABEL IN PART. (Drum) "Strong Cobb Arner, Inc. * * * Cleveland, Ohio * * * Manufactured for Reese Chemical Company Appetite Depressant Tablets * * * Formula contains * * * Phenylpropanolamine Hydrochloride 25 mg. * * * [or "Formula contains * * * Benzocaine 15 mg. Phenylpropanolamine Hydrochloride 25 mg. Procaine Hydrochloride 35 mg."] one tablet ½ hour before meals as an appetite depressant"; and (btl.) "Appetite Depressant Tablets [or "Dexaphene Appetite Depressant Tablets"] A Pleasant Way to Help Decrease Your Desire For Food Distributed by The Reese Chemical Co., Cleveland 6, Ohio * * * Each Tablet Contains: Phenyl Propanolamine Hydrochloride 25 mg." and "Super Dexaphene [or "Dexaphene Forté"] A Pleasant Way to Help Decrease Your Desire for Food Distributed by The Reese Chemical Co. Cleveland 6, Ohio Each Tablet Contains: Procaine 35 mg. Benzocaine 15 mg. Phenyl Propanolamine Hydrochloride 25 mg."

RESULTS OF INVESTIGATION: The article in the bottles was repacked from bulk drums by the dealer, Reese Chemical Co.

LIBELED: 5–21–64, N. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the labeling of the article (bulk and repack) contained false and misleading representations that the article was adequate and effective as an appetite depressant and to help decrease desire for food.

DISPOSITION: 7–2–64. Default—destruction.

*See also Nos. 8081, 8093, 8111–8118.

8125. Obesity Control tablets. (F.D.C. No. 50130. S. No. 3–127 A.)

QUANTITY: 10,000 tablets in a bulk drum and 3 repacked 50-tablet btls., at Leaksville, N.C., in possession of Chandler Chemical Co.

SHIPPED: 8–12–62, from Brooklyn, N.Y.

LABEL IN PART: (Btl.) "Obesity Control Tablets For effective appetite control to help in weight reduction (each tablet contains Phenylpropanolamine Hydrochloride – 25 mgm.) Caution * * * Manufactured For Chandler Chemical Co. Draper, N.C."

ACCOMPANYING LABELING: Additional repack-bottle labels.

RESULTS OF INVESTIGATION: Part of the article had been repacked from the bulk drum, by the dealer, into the bottles.

LIBELED: 5–13–64, M. Dist. N.C.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to control appetite in weight reduction.

DISPOSITION: 6–10–64. Default—destruction.

8126. Trim'N Slim capsules. (F.D.C. No. 50109. S. No. 1–198 A.)

QUANTITY: 118 21-capsule boxes, packed 1 doz. to a display ctn., at Atlanta, Ga.

SHIPPED: Between 3–28–64 and 3–30–64, from Miami, Fla., by Barry-Martin Pharmaceuticals, Inc.

LABEL IN PART: (Box) "Time Disintegration Capsules Trim'N Slim Capsules Each Capsule Contains Phenyl Propanolamine Hcl 50 mg. * * * One Capsule Daily * * * Dist. by Barry-Martin Pharmaceuticals, Inc., Miami, Florida."

ACCOMPANYING LABELING: Leaflet in box reading in part "Suggested Dietary Regimen"; display carton reading in part "Slenderize * * * Curb Your Appetite."

LIBELED: On or about 5–4–64, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the name of the article, *"Trim'N Slim Capsules,"* and certain statements in its labeling, represented and suggested that the article was adequate and effective as an aid in appetite suppression in the dietary control of obesity, and would curb the appetite, and slenderize, which name and statements were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: 6–15–64. Default—destruction.

8127. Proteinail. (F.D.C. No. 50104. S. No. 43–142 A.)

QUANTITY: 46 1½-oz. tubes, 9 3-oz. btls., 9 6-oz. btls., 3 32-oz. btls., and 2 1-gal. btls., at Salt Lake City, Utah.

SHIPPED: Between 4–1–63 and 12–26–63, from North Hollywood, Calif., by Nu-Tress Laboratories, Inc.

LABEL IN PART: "Proteinail * * * Protein Enriched! A High Potency Organic Protein Food Which Restores Normal Protein To Damaged Nails. * * * Nutress Laboratories, Inc. North Hollywood, California."

RESULTS OF INVESTIGATION: Partial analysis showed that the article contained, in the 3-oz. bottles, no detectable protein material and, in the 7-oz. bottles, approximately 0.005 percent nitrogeneous material calculated as protein.

LIBELED: 5–6–64, Dist. Utah.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was protein-enriched; made nails diamond-hard; hardened nails and softened cuticle; made nails grow long and strong; was a treatment for all brittle, soft, weak, or thin nails; was a high-potency organic protein food for the nails which restored normal protein to damaged nails; that proper use of the article would insure healthy, strong nails and smooth, soft cuticles; eliminated hangnails; showed immediate improvement; that five or six treatments would guarantee harder nails and softer cuticles; and softened skin on hands, arms, and rough elbows, and on callouses.

DISPOSITION: 7–13–64. Default—destruction.

8128. Emulsion Gimenez. (F.D.C. No. 49077. S. Nos. 82–922/3 V.)

QUANTITY: 41 cases, each containing 36 6-oz. btls., and 19 cases, each containing 36 10-oz. btls., at Newark, N.J.

SHIPPED: 3–8–63 and 5–6–63, from Catano, P.R., by Emulsion Gimenez.

LABEL IN PART: (Btl.) "Emulsion Gimenez * * * Active Ingredients Cod Liver Oil, Extract of Ipecacuana, combined in an emulsion * * * Emulsion Gimenez Catano, Puerto Rico * * * Dose."

ACCOMPANYING LABELING: Carton inserts entitled "Emulsion Gimenez The Product that has made Puerto Rico Famous."

LIBELED: 6–21–63, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of arthritis, lack of appetite, rickets, insomnia, loss of weight, chronic catarrh, colds and asthma; and to promote immunity to disease.

DISPOSITION: 8–20–63. Consent—claimed by Goyescas Corp., Newark, N.J., for relabeling.

8129. Alpha Rex tablets. (F.D.C. No. 49886. S. Nos. 60–597/8 X.)

QUANTITY: 759 205-tablet boxes and 220 80-tablet boxes at St. Joseph, Mo.

SHIPPED: Between 1–1–63 and 1–31–63, from Council Bluffs, Iowa, by Dwarfies Corp.

LABEL IN PART: (Box) "Alpha Rex Aids Temporary Relief of Aches and Pains Associated with Arthritis and Rheumatism with the White Tablets Serving As A Nutritional Supplement * * * Directions (For Adults Only) * * * Each Green * * * Tablet Contains: * * * Ascorbic Acid . . . 15 milligrams * * * Each 4-White Tablets Contains: Calcium . . . 750 Milligrams Phosphorous . . . 560 Milligrams * * * Vitamin D–2 (crystalets) . . . 1300 USP Units."

ACCOMPANYING LABELING: Box insert reading in part "Alpha-Rex * * * The White tablets, even by themselves alone, can prove highly valuable."

LIBELED: On or about 3–4–64, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the white tablets alone were effective for relief of arthritis and rheumatism.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–12–64. Consent—destruction.

8130. Butac capsules. (F.D.C. No. 50323. S. Nos. 7-907/8 A).

QUANTITY: 3 cases, each containing 240 12-capsule pkgs., 3 cases, each containing 372 12-capsule pkgs., 7 boxes, each containing 14 12-capsule pkgs., and 1 box containing 10 12-capsule pkgs., at Baltimore, Md.

SHIPPED: 4-18-63 and 7-30-63, from New York, N.Y., by Davis-Edwards Pharmacal Corp.

LABEL IN PART: (Pkg.) "For Day And Night Relief Butac continuous action capsules for the temporary relief of nasal congestion due to colds and hay fever * * * Timed Disintegration Capsules * * * Distributed by National Pharmaceutical Mfg. Co., Baltimore 2, Md. * * * Each Capsule Contains Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Scopalamine Hydrobromide 0.014 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Phenylpropanolamine Hydrochloride 50.0 Mgm. Chlorpheniramine Maleate 1.0 Mgm. Pheniramine Maleate 12.5 Mgm. Dosage: Adults, one capsule in the morning, and one before retiring."

LIBELED: 6-29-64, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that a single *Butac capsule* containing the amounts of ingredients declared in the label would provide 12 hours of continuous relief of excessive nasal discharge, running nose, watering of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 2-5-65. Default—destruction.

8131. Gelatin. (F.D.C. No. 47729. S. No. 68-417 T.)

QUANTITY: 142 1-lb. ctns. at Milwaukee, Wis.

SHIPPED: 6-11-62, from Grayslake, Ill., by Grayslake Gelatin Co.

LABEL IN PART: (Ctn.) "Grayslake Pure Unflavored Gelatin * * * Grayslake Gelatin Co. Producers, Box 208, Grayslake, Illinois."

LIBELED: 7-12-62, E. Dist. Wis.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of digestive disorders, ulcers, and colitis, and to promote the digestion of food; to reduce; and to enhance skin tone.

DISPOSITION: 7-21-64. Default—destruction.

8132. Benecol. (F.D.C. No. 49586. S. Nos. 78-223 X, 78-232 X.)

QUANTITY: 900 8-oz. btls. at Sacramento, Calif.

SHIPPED: Between 3-21-63 and 7-29-63, from Las Vegas, Nev., by Lovelite Cosmetics, Inc.

LABEL IN PART: (Btl.) "Benecol Beneficial in the Control of Stomach Disorders-for the Control of Common Diarrhea-for Upset Stomach and Indigestion A Product of Health Research Division of Lovelite Cosmetics, Inc. * * * Las Vegas, Nevada * * * Bentonite Used as an Absorptive in the Symptomatic Treatment of."

ACCOMPANYING LABELING: Leaflet reading in part "Benecol * * * Bentonite Serves as an Absorbent Aid in Detoxification of the Intestinal Canal * * * in the Treatment of Diarrhea. The Causative Factors of the Diarrhea Were Virus Infection, Food Allergy, Spastic Colitis and Food Poisoning."

LIBELED: 1–10–64, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of stomach disorders, enteritis, diarrhea, food allergy, spastic colitis, food poisoning, and ulcerative colitis; and 502(e)(1)(A)(ii)—the label of the article failed to bear the established name of each active ingredient.

DISPOSITION: 4–30–64. Default—destruction.

8133. Firmatone device and lotion. (F.D.C. No. 47663. S. No. 61–060 T.)

QUANTITY: 13 devices and 13 6-oz. btls. of lotion at Flint, Mich.

SHIPPED: Between 9–1–61 and 6–5–62, from Hollywood, Fla., by Richard L. Hobson and GlamRon, Inc.

LABEL IN PART: (Device) "Firmatone Made by GlamRon, Inc., Hollywood, Florida" and (btl.) "Firmatone Contact-Lotion Shake well before applying to sponges. * * * contains Allantoin wonderful skin food and fabulous moisturizer Made by GlamRon Inc. Hollywood, Fla."

ACCOMPANYING LABELING: Leaflets entitled "Firmatone Guarantee," "The New Magic 'Electronic' Wrinkle Remover Firmatone," and "Firmatone * * * Thrilling News."

RESULTS OF INVESTIGATION: The device was a battery-operated, transistorized circuit to produce electrical impulses to be applied to the body through sponge applicators.

LIBELED: 6–12–62, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for rejuvenating the face by eliminating poor skin texture, dry skin conditions, sagging facial contours, skin wrinkles, flabby facial muscles, facial puffiness due to poor circulation, and to create a healthier, more youthful appearance.

DISPOSITION: 8–8–63. Default—2 devices delivered to the Food and Drug Administration; remainder destroyed.

8134. Peerless C-Sacral Belt. (F.D.C. No. 49930. S. No. 24–223 A.)

QUANTITY: 250 devices at Chicago, Ill., in possession of Brooks Appliance Co., Inc.

SHIPPED: 11–25–63, from Marshall, Mich.

LABEL IN PART: (Device) "Peerless C-Sacral Belt."

ACCOMPANYING LABELING: Leaflets entitled "Back and Neck Pain Conservative Treatment by Prolotherapy," "Prolotherapy for Sciatica from Weak Pelvic Ligaments and Bone Dystrophy," "Whiplash Injury and Other Ligamentous Headache–Its Management with Prolotherapy," "Prolotherapy For Headache," and "Dr. Hackett's C-Sacral Belt."

RESULTS OF INVESTIGATION: The last leaflets described above had been printed on order of the dealer on approximately 3–11–63. The other leaflets had been shipped from Compton, Calif. Examination indicated the device to be a 2-inch-wide elastic belt intended to be worn below the iliac crest around the body.

LIBELED: 3–19–64, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was an adequate and ef-

fective treatment for low back pain; sacro-iliac involvements, sciatica and arthritic conditions, fractured ribs; pleurisy, weak ligament and tendon attachments to bone, congenital deformities, neuritis, weak pelvic ligaments and bone dystrophy, lumbosacral joint ligament instability, whiplash injury, and other ligamentous headache, and pain in the head and neck.

DISPOSITION: 4–14–64. Consent—claimed by Brooks Appliance Co., Inc., for relabeling.

8135. **Veltron massaging devices.** (F.D.C. No. 49970. S. Nos. 24–301/2 A.)

QUANTITY: 67 *chin massagers* and 21 *foot and body massagers*, at Chicago, Ill.

SHIPPED: Between 10–8–63 and 2–1–64, from Anaheim, Calif., and New York, N.Y., by Veltron Products, Inc., and Henry H. Brown.

LABEL IN PART: (Ctn.) "Veltron Electronic Chin Massager * * * A Product of The S. L. McNair Corporation, Anaheim, California" and (device) "Electronic Veltron Massager * * * A Product of S. L. McNair Corp., Anaheim, Calif."; (ctn.) "Veltron Foot and Body Massager" and (device) "Warning Do Not Immerse Vibrator in water * * * A Product of The S. L. McNair Corporation, Anaheim, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Veltron * * * Electronic Under Chin Massager" and "Veltron * * * Hydrotherapy and Body Massager"; cards entitled "Veltron * * * Hydrotherapy and Body Massager."

RESULTS OF INVESTIGATION: The *chin massager* consisted of a cylinder with an electrical cord attached to the bottom, and a foam-rubber pad at the top, which was in the shape of a concave flap with a rubber chin-strap included for attachment to the flap part of the cylinder.

The *body massager* consisted of a plastic tub $6\frac{15}{16}$'' high, $12\frac{7}{8}$'' long, and $11\frac{7}{8}$'' to $9\frac{7}{8}$'' wide, on a wire rack which extended just beyond the tub, into which rack a cylinder was fitted when used for foot massage. The cylinder was to be removed from the rack when used for body massage.

LIBELED: 4–10–64, N. Dist. Ill.

CHARGE: *Chin massager*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for avoiding or correcting unsightly underchin and throat muscles and sagging, flabby, underchin and throat wrinkles; and that treatment with the device was like having 1,800 magic fingers massaging one's throat at one time.

Body and foot massager, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for aches and pains, rheumatism, arthritis, poor circulation, muscle fatigue, tenseness of calf and thigh muscles, musclebound conditions, and tensions.

DISPOSITION: 9–17–64. Consent—claimed by Veltron Products, Inc., for relabeling.

8136. **Negative ion generator.** (F.D.C. No. 49898. S. No. 6–521 A.)

QUANTITY: 5 unlabeled devices at Washington, D.C.

SHIPPED: 11–30–63, from Exton, Pa., by International Trade Co.

ACCOMPANYING LABELING: Circular entitled "Ion-Lite The Lamp of the Future Today"; paper reading in part "What are Ions."

RESULTS OF INVESTIGATION: Examination indicated the device to be a small lamp-light device containing two bulbs wired in series. One bulb was an ordinary 40-watt incandescent light, the other was a General Electric ultraviolet light. In use, the lamp allegedly enriched the air of the room with negative ions in addition to supplying normal light.

LIBELED: 3-2-64, Dist. Columbia.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for tensions, uplifting moods, hay fever, bronchial asthma, tranquilizing the injured, quick-healing burns, killing airborne bacteria, preventing the spread of viruses, tuberculosis, ulcers, arthritis, rheumatism, shaping personality, viral infection, cancer, calming the nerves, high blood pressure, slow healing wounds and ulcers.

DISPOSITION: 4-22-64. Default—delivered to the Food and Drug Administration.

8137. Cosray Electronic device. (F.D.C. No. 48663. S. No. 2-787 V.)

QUANTITY: 1 device at Pensacola, Fla.

SHIPPED: 11-13-62, from Salt Lake City, Utah, by Research Institute, Inc. (T. Henry Moray), lessor of the device.

LABEL IN PART: (Tag on device) "Research Institute, Inc. * * * Cosray Salt Lake City, Utah."

ACCOMPANYING LABELING: Booklets entitled "Theory of Application and Treatment With Cosray Electronic Therapy * * * Research Institute, Inc. Salt Lake City, Utah" and "Photo Actinia Oxygen Therapy by Electric Reaction, by T. Henry Moray"; and sheet entitled "A Preliminary Report of Tests Using the Moray Therapeutic Machine."

RESULTS OF INVESTIGATION: Investigation indicated that the device was a large wooden cabinet containing electrical circuitry for the production of high-voltage, high-frequency, low-intensity currents to be applied to the body through a variety of glass tubes and metal electrodes. The various parts and cabinet of the device had been shipped disassembled, as above, and had been assembled by John E. Moray, at Pensacola, Fla., and had thereafter been delivered by him to the lessee-possessor.

LIBELED: 3-6-63, N. Dist. Fla.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for rundown condition, arthritis, sinus-catarrh, pharyngitis, whooping cough, bronchitis, asthma, ulcers, hemorrhoids, tumors, fibroids, kidney infection, liver infection, brain and nervous conditions, cataracts and other eye diseases, skin diseases, general germ infections, paralysis, and bacterial mycotic diseases.

DISPOSITION: On 5-9-63, Research Institute, Inc., served a motion to vacate the default entered on 4-3-63, on the following grounds:

1. Lack of jurisdiction in that the described device is not a subject of interstate commerce.

2. Lack of due process of law. The Research Institute, Inc., is the owner of the above-described device, and, although the Libel of Information pleads the address of the Research Institute, Inc., no service was made, nor was any

notice of impending action given. It was necessary for the owner to seek out and determine what was happening to its property.

3. The Research Institute, Inc., has a good and valid defense to the Libel of Information which it should be able to assert, and its failure to previously plead was not due to neglect or inadvertence on its part but solely that it knew nothing of the suit.

The Research Institute, Inc., a Utah corporation, further moved the above-entitled court to dismiss the action on the following ground:

1. Lack of jurisdiction over the subject matter.

On 8-20-63, the court rendered the following order:

CARSWELL. *District Judge:* "This matter was submitted to the Court on memorandum filed by the libelant, United States, and by Research Institute, Inc.

"This civil *in rem* proceeding was initiated by the United States pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 ff. Basically, the libel of information alleges that the article involved is a device and was misbranded when introduced, while in, and while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 352(a) in that its labeling contains false and misleading statements.

"Upon monition being issued by this Court the device was seized by the United States Marshal, and following notice and publication when no person appeared a default judgment was entered against the article on April 3, 1963.

"Research Institute, Inc., of Salt Lake City, Utah, now moves the Court for an order vacating the default and to dismiss the action. The basis for the motion to vacate default is said to be that the Court lacks jurisdiction because the device 'is not a subject' of interstate commerce; that due process of law is lacking because of lack of notice; that the moving party has a good and valid defense which it should be allowed to assert. The motion for dismissal is based upon an alleged lack of jurisdiction over the subject matter.

"Libelant, the United States, submits that the movant has no standing in this case; that there is no good cause for setting aside default in this action; and that there is no basis for dismissal, so that both motions should be denied.

"Since the filing of the Government's memorandum on June 20, 1963, in which it was pointed out that Research Institute, Inc., had not filed a claim against the article, Research has filed, on August 15, 1963, such a claim executed in proper form by its President. Upon the face of this the Court concludes that Research Institute, Inc., does now have standing to be heard in this case.

"The Court also concludes, however, that the entry of default should not be set aside. This determination is made in the exercise of the discretion of this Court under the provisions of Rule 55(e), Federal Rules of Civil Procedure. While it is clear that doubt should be resolved in favor of setting aside default, the facts disclosed on this record simply do not call for such action. There is a clear showing here that the claimant did, in fact, have actual knowledge of the pendency of this litigation with adequate time in which to file its claim.

"Research Institute, Inc., also moves for dismissal of the action. Accepting all the facts pleaded in the information for libel in the light most favorable to plaintiff it is clear that there is no basis whatsoever for dismissing this action. See *Mannings* v. *Board of Public Instruction*, 277 F. 2d 370, for a recent (1960) expression of the Fifth Circuit in this regard. The suggestion of Research Institute, Inc., that this Court lacks jurisdiction is made with reliance upon *United States* v. *An Article of Device. . . . 'Gonsertron Corporation,' etc.*, 180 F. Supp. 52 (E.D. Mich, 1959), which held that a device is not subject to the jurisdiction of the Act where the only component parts shipped in interstate commerce were several commonly used components which lost their identify within the newly manufactured device. Section 321(h) of the Act defines 'device' as meaning:

> . . . instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (2) to effect the structure or any function of the body of man or other animals.

The subject parts here were in no sense similar to those in *Gonsertron*, but fall instead under the ambit of *United States* v. *39 Cases . . . Korleen, etc.*, 192 F. Supp. 51 (E.D. Mich. 1961), where the *Gonsertron* decision was clarified by Judge Levin, who had rendered it, and also *United States* v. *40 Cases . . . Pinocchio Brand, etc.*, 289 F. 2d 343 (C.A. 2, 1961).

"It is, therefore, upon consideration, hereby ORDERED:

"1. Motion to vacate default judgment is denied.

"2. Motion to dismiss the libel of information is denied.

"DONE AND ORDERED in Chambers at Tallahassee this 20th day of August 1963."

On 9–17–63, the court ordered that the article be returned to the claimant under bond; that the Food and Drug Administration inspect the article; that the claimant shall have 90 days after such inspection to correct any required deficiencies to the article; that, if the Food and Drug Administration determines that the article was not subject to conform to the regulations of the Federal Food, Drug, and Cosmetic Act, or could not be improved so as to conform to the Act, then it was to be destroyed; that if it was determined by that agency that the article complied, or could comply with the Act, then the article could be returned to the claimant.

On 3–19–64, after the Food and Drug Administration concluded that the device was of no value for any therapeutic or diagnostic purpose, and that it could not be brought into compliance with the Federal Food, Drug, and Cosmetic Act, the article was destroyed.

8138. Jayne Mansfield Sunlamp. (F.D.C. No. 49945. S. Nos. 7–899 A, 7–902 A.)

QUANTITY: 62 ctns., each containing unassembled parts for one device, at Preston, Md.

SHIPPED: 12–17–63, from Richmond, Va., by Parker Sales, Inc.

LABEL IN PART: (Ctns.) "From Parker Sales, Inc. * * * Richmond, Virginia To Castelli Engineering Company Bridgeport, Pennsylvania" and "Jayne Mansfield Health-Tan Sunlamp Can't Burn From Parker Sales, Inc. * * * Richmond, Virginia To Castelli Engineering Company Bridgeport, Pennsylvania"; (bulb) "Jayne Mansfield Sunlamp * * * Richmond, Va. U.S.A." and (bulb) "Health-Tan Sunlamp Richmond, Va.," and (filters) "Jayne Mansfield Health-Tan Sunlamp Richmond, Va.," (filters in envelope) "Can't Burn—Health-Tan Sunlamp Filter," or "Clear Tanning Filter."

ACCOMPANYING LABELING: Leaflets entitled "Safe! * * * Jayne Mansfield Patented Health-Tan Sunlamp with exclusive Can't Burn Feature!" "Operating Instructions," and "Assembly of Health Tan Sun Lamp"; and envelope in carton "Operating Instructions."

RESULTS OF INVESTIGATION: The labeling and photographs taken of the article indicated that it was an electrical lamp fixture containing a 275-watt ultraviolet lamp and holder for Mylar and/or acetate filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: On or about 3–26–64, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving tired back, sinus conditions, stiff neck, arthritic-like pains, skin problems, aching muscles, and for toning the skin; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the article could be used as a "sunlamp that can't burn."

DISPOSITION: 4–29–64. Default—destruction.

8139. Safe-T-Sun Health-Tan sun lamps. (F.D.C. No. 49667. S. No. 54–498 X.)

QUANTITY: 7 assembled devices and 26 unassembled devices at Nashville, Tenn.

SHIPPED: 10–15–63, from Bridgeport, Pa., by Richard Kastner Co., Inc.

LABEL IN PART: (Lamp bulb) "Safe-T-Sun Health Tan Sun Lamp" and (filter "Safe-T-Sun Corporation Health Tan Sun Lamp, Williamsburg, Virginia."

ACCOMPANYING LABELING: Pamphlets entitled "Yes! This Is the Amazing New Safe-T-Sun Health Tan Sun Lamp That Can't Burn."

RESULTS OF INVESTIGATION: The article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: 12–27–63, M. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of adolescent and other skin problems, relieving tired back, arthritic- and rheumatic-like pains, chills, stiff neck and back; and that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning and that infants could be exposed for hours without the slightest harm; and that the device could be used as a "sunlamp that can't burn."

DISPOSITION: 2–28–64. Default—the bulbs were destroyed and the lamps were delivered to a charitable institution.

DRUG FOR VETERINARY USE*

8140. Medicated feed. (F.D.C. No. 49751. S. No. 61–463 X.)

QUANTITY: 180 blocks, each containing 33⅓-lbs., at Wichita, Kans.

SHIPPED: 10–19–63, from Kansas City, Mo., by Pay Way Feed Mills, Inc.

LABEL IN PART: "Pay Way Y Cattle Guard Protein Block Pay Way Feed Mills, Inc. * * * Kansas City, Mo. Medicated * * * Active Ingredients Ethylene Diamine Dihydroiodide (100 grams/ton) 50 milligrams per lb Guaranteed Analysis * * * Ingredients * * * Warning * * * Feeding Directions."

RESULTS OF INVESTIGATION: Analysis showed that the article contained .037 percent iodine.

LIBELED: 1–31–64, Dist. Kans.

CHARGE: 502(a)—when shipped, the label bore statements which represented and suggested that the article was adequate and effective for prevention of lumpy-jaw and infections of the upper respiratory tract in cattle, which statements were false and misleading, since the article was not adequate and effective for such purposes.

DISPOSITION: 5–28–64. Default—delivered to a charitable institution.

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*See also Nos. 8109, 8119–8122.

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Effervescing Midy Granules	[3] 8093
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Feed, medicated	8120, 8121, 8140
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Mansfield, Jayne, Sunlamp	8138
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Neuritis, remedies for. *See* Rheumatism, remedies for.	
Nitroglycerin and phenobarbital tablets	8112

[1] **(8082) Injunction issued.**
[2] (8137) Seizure contested. Contains order of the court.
[3] **(8088, 8093) Seizure contested.**

	N.J. No.
Obesity Control tablets	8125
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Turkey feed, medicated	8119
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Basin Bean Co.:	
clay	8109
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Corn Products Co.:	
Kasco Mom 'N' Pup Food	8122
See also Best Foods Div.	
Davis-Edwards Pharmacal Corp.:	
Butac capsules	8130
dextro-amphetamine sulfate capsules	8096

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[1] (8082) Injunction issued.
[3] (8088, 8093) Seizure contested.
[4] (8091) Prosecution contested.

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Dixie Laboratories:
mineral oil 8111
Dwarfies Corp.:
Alpha Rex tablets 8129
Emulsion Gimenez:
Emulsion Gimenez 8128
Fougera, E., & Co., Inc.:
Effervescing Midy Granules 8093
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Angibarb capsules and Angitol capsules 8106
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Firmatone device and lotion 8133
Grayslake Gelatin Co.:
gelatin 8131
Hawk, C. L., M.D.:
Laetrile, Hoxsey treatment, Krebiozen, Mucorhicin, Lincoln treatment, Koch cancer treatment, and Siccacell [1] 8082
Health Research Div., Lovelite Cosmetics, Inc.:
Benecol 8132
Hobson, R. L.:
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Hudson Vitamin Products, Inc.:
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Kastner, Richard, Co., Inc.:
Safe-T-Sun Health-Tan sun lamps 8139
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Kingston Laboratories, Ltd.:
chlorprophenpyridamine maleate timed disintegration capsules 8113
L. M. Research Products, Inc.:
Coftoc Cough Medicine 8084
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Effervescing Midy Granules [3] 8093

N.J. No.

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Masters & Masters Clinic:
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Moffet Laboratories, Inc.:
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Proteinail 8127
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[1] (8082) Injunction issued.
[2] (8137) Seizure contested. Contains order of the court.
[3] (8088, 8093) Seizure contested.

	N.J. No.
Pay Way Feed Mills, Inc.:	
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Pharmakon A G:	
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Reese Chemical Co.:	
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Cosray Electronic device	[2] 8137
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Abaphage tablets	8085
Rhein-Chemie:	
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S & R Laboratories, Inc.:	
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Safe-T-Sun Corp.:	
Safe-T-Sun Health-Tan sun lamps	8139
Sanabo:	
Wobe enzymes and prepared animal tissues	8083
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peyote buttons	[4] 8091
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[1] (8082) Injunction issued.
[2] (8137) Seizure contested. Contains order of the court.
[4] (8091) Prosecution contested.

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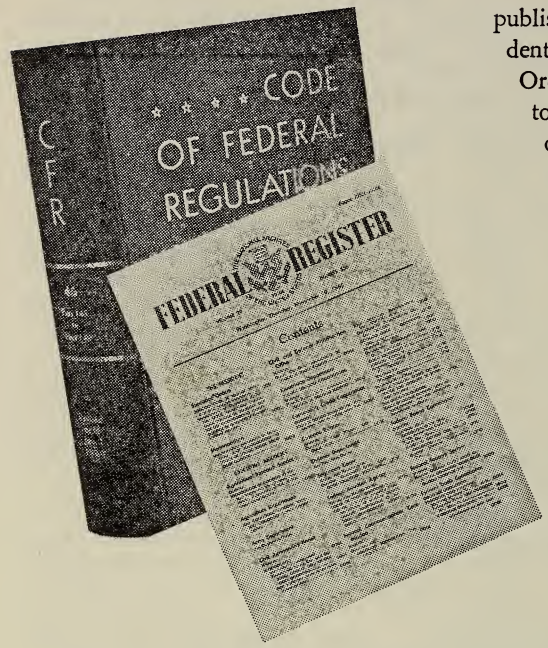

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D.D.N.J., F.D.C. 8141–8180 Issued September 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8141–8180

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *September 28, 1965.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

8141. (F.D.C. No. 49193. S. Nos. 28–657/8 T, 28–833 T.)

INFORMATION FILED: 5–6–64, N. Dist. Iowa, against **James Kapparos, Dubuque, Iowa, and 7–15–64, against Carmalita Kinny, Dubuque, Iowa.**

CHARGE: Between 12–6–61 and 12–12–61, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–6–64, Kapparos—$150 fine; 7–15–64, Kinny—6 months in prison suspended, and probation for 1 year.

8142. (F.D.C. No. 50471. S. Nos. 45–341/5 A.)

INFORMATION FILED: 10–1–64, Dist. Wyo., against **Jesse Jake Baskins (employee of a truck stop), Pine Bluffs, Wyo.**

CHARGE: Between 1–2–64 and 3–9–64, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–15–64. $50 fine, and probation for 6 months.

8143. (F.D.C. No. 50019. S. Nos. 259 X, 267 X, 1–926 X, 1–931 X.)

INFORMATION FILED: 9–29–64, N. Dist. Ga., against **Gerald T. Cantrell, Gainesville, Ga.**

CHARGE: Between 7–31–63 and 8–6–63, *amphetamine sulfate tablets* were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 10–22–64, and was completed with the return of a verdict of guilty to all counts by the jury. On 10–28–64, the court sentenced the defendant to imprisonment of 1½ years, of which 1 year was suspended, and placed defendant on probation for 2 years.

8144. (F.D.C. No. 50802. S. Nos. 9–720 A, 10–716 A.)

INFORMATION FILED: 11–20–64, W. Dist. Va., against **Arville Shank, Harrisonburg, Va.**

CHARGE: Between 8–18–64 and 9–1–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–30–64. $730 fine, sentence of 1 year suspended, and probation for 3 years.

8145. (F.D.C. No. 50803. S. No. 10–162 A.)

INFORMATION FILED: 11–20–64, W. Dist. Va., against **David L. McAlister, Dayton, Va.**

CHARGE: On 10–6–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–30–64. $700 fine, sentence of 1 year in prison suspended, and probation for 3 years.

8146. (F.D.C. No. 48549. S. Nos. 44–366 T, 44–376 T, 44–746 T, 44–781 T, 44–786 T.)

INFORMATION FILED: 6–12–63, E. Dist. Pa., against **John J. Pitcherella, t/a Pitcherella's Pharmacy, Coatesville, Pa.**

RESULTS OF INVESTIGATION: Investigation showed that the *amphetamine sulfate tablets* had been fabricated at Philadelphia, Pa., from amphetamine sulfate which had been shipped in interstate commerce.

CHARGE: Between 5–3–62 and 5–21–62, *amphetamine sulfate tablets* were dispensed 3 times and *Disulfiram tablets* were dispensed once, without a prescription; and *meprobamate tablets* were dispensed once upon request for a prescription refill without obtaining authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 11–30–64. $1,500 fine.

8147. (F.D.C. No. 49190. S. No. 45–555 V.)

INFORMATION FILED: 4–3–64, W. Dist. Mo., against **Leonard Havener, Springfield, Mo.**

CHARGE: On 3–8–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–9–64. Imprisonment for 30 days.

8148. (F.D.C. No. 49543. S. Nos. 63–901 R, 63–903 R, 17–111 T, 17–118/19 T.)

INFORMATION FILED: 5–22–64, S. Dist. Ohio, against **Mrs. Carrie Thompson (employee of physician), Columbus, Ohio.**

CHARGE: Between 8–2–61 and 9–12–62, *amphetamine sulfate tablets* were dispensed 4 times and *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–9–64. Imprisonment for 2 years.

8149. (F.D.C. No. 50804. S. Nos. 10–163/5 A, 10–721/2 A, 10–733 A.)

INFORMATION FILED: 11–20–64, W. Dist. Va., against **Carl Royal, Galax, Va.**

CHARGE: Between 10–7–64 and 10–28–64, *amphetamine sulfate tablets* were dispensed 5 times and *phenobarbital tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–30–64. $2,170 fine, 1 year in prison suspended, and probation for 3 years.

8150. (F.D.C. No. 50367. S. Nos. 61–481 A, 62–165/6 A, 62–171 A.)

INFORMATION FILED: 7–2–64, S. Dist. Calif., against **James Caballero, Los Angeles, Calif., and Santiago Herrera Reynozo (barber shop owner), Los Angeles, Calif.**

CHARGE: Between 4–30–64 and 6–4–64, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Caballero to 3 counts; by Reynozo to 1 count.

DISPOSITION: 8–28–64. Caballero—imprisonment for 3 years; Reynozo—imprisonment for 1 year.

8151. (F.D.C. No. 48514. S. Nos. 59–561/77 T.)

INFORMATION FILED: 11–30–62, N. Dist. Ala., against **Arlie Turner and Ruby Turner, Hulaco, Ala.**

CHARGE: Between 9–25–62 and 11–1–62, *amphetamine sulfate tablets* were dispensed 7 times and *methamphetamine hydrochloride tablets* were dispensed 10 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–13–64. Arlie Turner—imprisonment for 2 years; Ruby Turner—probation for 2 years.

8152. (F.D.C. No. 50361. S. Nos. 54–602/3 V, 54–713/18 V.)

INDICTMENT RETURNED: 8–28–64, N. Dist. Iowa, against **Gustov Wolfson, Chicago, Ill.**

ALLEGED VIOLATION: Between 4–13–63 and 4–30–63, *amphetamine sulfate tablets* and *amphetamine sulfate capsules* were each dispensed twice without a prescription, at a truck stop in Cedar Rapids, Iowa.

PLEA: Guilty.

DISPOSITION: On 10–15–64, the case was transferred to the Northern District of Illinois. On 12–17–64, the individual was sentenced to imprisonment for 1 year, which was suspended, and was placed on probation for 2 years.

8153. (F.D.C. No. 49144. S. Nos. 15–661 X, 15–663 X, 15–665/71 X, 15–675/80 X, 15–701 X, 17–441 X, 17–458/9 X.)

INDICTMENT RETURNED: 9–24–63, E. Dist. Ky., against **Paul Anness, Marshall Robinson, Winona Sears, Alben Carlisle Jump, a/k/a Johnny Jump, and Martha Padgett, Covington, Ky.**

CHARGE: Between 6–10–63 and 8–27–63, *amphetamine sulfate tablets* were dispensed 13 times, *Nembutal capsules* were dispensed 4 times, and *Dexamyl tablets* were dispensed once without a prescription.

PLEA: Guilty by Jump to 2 counts; by Padgett to 3 counts; by Sears to 5 counts; by Robinson to 6 counts; and by Anness to 10 counts.

DISPOSITION: 11–6–63. Anness—imprisonment for 12 months; Sears—imprisonment for 6 months; Robinson—imprisonment for 6 months; Jump—imprisonment for 6 months; Padgett—imprisonment for 6 months suspended, and probation for 1 year.

8154. (F.D.C. No. 48186. S. No. 87–819 T.)

INFORMATION FILED: 11–14–61, S. Dist. Ga., against **Paul Lee Parker, Hinesville, Ga.**

CHARGE: On 3–31–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–22–61. $100 fine, and probation for 2 years.

8155. (F.D.C. No. 50621. S. Nos. 4–675/7 X, 7–284 A.)

INFORMATION FILED: 11–9–64, M. Dist. N.C., against **Walter Holmes Adair, t/a Adair's Drug Store, Roxboro, N.C.**

CHARGE: Between 12–6–63 and 1–16–64, *amphetamine sulfate tablets* and *dextro-amphetamine sulfate capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12–23–64. $1,000 fine.

8156. (F.D.C. No. 50357. S. Nos. 7–293/5 A, 7–299/302 A.)

INFORMATION FILED: 9–8–64, W. Dist. S.C., against **Ralph O. McMillan, t/a Cowpens Truck Stop, Cowpens, S.C., William R. Wall, and Harold Hershell Evans, Gaffney, S.C.**

ALLEGED VIOLATION: Prior to 2–5–64 and continuing to 2–13–64, McMillan, Wall, and Evans conspired (count 1) to commit offenses and cause the commission of offenses prohibited by the Federal Food, Drug, and Cosmetic Act with respect to misbranding quantities of *amphetamine-containing tablets* by dispensing and causing the dispensing of such drugs without a prescription.

It was part of the conspiracy that McMillan would and did obtain from various suppliers, quantities of *amphetamine-containing tablets* which had been manufactured outside the State of South Carolina; that McMillan would deliver and cause to be delivered to Wall and Evans, various quantities of such *amphetamine-containing tablets*, for dispensing without a prescription; that McMillan would refer to Wall and Evans, prospective customers to whom *amphetamine tablets* would be dispensed without prescription; and that Wall and Evans would dispense and cause to be dispensed quantities of such *amphetamine-containing tablets* to customers without a prescription, contrary to the provisions of the Act.

In pursuance of the conspiracy, and to effect the objects of it, McMillan, Wall, and Hershell committed various overt acts, among others the following: (a) On 2–5–64, McMillan had a conversation on Cherokee Avenue Extension, Gaffney, S.C., with a Government agent regarding the price at which *amphetamine-containing drugs* could be obtained, and agreed to supply quantities of such drugs to the agent; (b) on 2–5–64, following the above discussion, McMillan introduced the Government agent to Wall; (c) on 2–5–64, Wall unlawfully dispensed to a Government agent four 5,000-tablet bottles containing *amphetamine sulfate tablets*, and one 5,000-tablet bottle containing *dextro-amphetamine sulfate tablets* without a prescription; (d) on 2–13–64, McMillan had a conversation at the Cowpens Truck Stop, Cowpens, S.C., with a Government agent concerning the cost of *amphetamine-containing tablets;* (e) on 2–13–64, Wall and Evans unlawfully dispensed to a Government agent four 5,000-tablet bottles containing *amphetamine sulfate tablets*, and one 5,000-tablet bottle containing *dextro-amphetamine sulfate tablets* without a prescription therefor.

In addition, between 2–5–64 and 2–13–64, *amphetamine sulfate tablets* (counts 2 and 5), and *dextro-amphetamine sulfate tablets* (counts 3 and 4) were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–5–64. McMillan—$3,000 fine, and imprisonment for 3 years; Wall—imprisonment for 3 years; Evans—imprisonment for 2 years.

8157. (F.D.C. No. 50030. S. Nos. 56–334 V, 7–281 X, 7–286 X.)

INFORMATION FILED: 7–29–64, Dist. R.I., against **Norwood Pharmacy, Inc., Warwick, R.I., and Max Broomfield (president and treasurer).**

CHARGE: Between 5–17–63 and 6–14–63, *dextro-amphetamine sulfate capsules* were dispensed twice upon request for prescription refills without obtaining authorization by the prescriber and *Deltamide tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–15–65. Each defendant—$300 fine.

8158. (F.D.C. No. 50365. S. Nos. 17–431/2 X.)

INFORMATION FILED: 8–4–64, S. Dist. Ohio, against **James E. Rollins, Kanauga, Ohio.**

CHARGE: On 9–13–63, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12–17–64. $250 fine, and probation for 1 year.

8159. (F.D.C. No. 50369. S. No. 15–081 X.)

INFORMATION FILED: 8–4–64, S. Dist. Ohio, against **Bernard Butcher, Chillicothe, Ohio.**

CHARGE: On 7–9–63, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–17–64. Probation for 2 years.

8160. (F.D.C. No. 48554. S. Nos. 3–155 T, 3–159/60 T, 3–570 T.)

INFORMATION FILED: 5–16–63, E. Dist. Va., against **Hubert O. Boyd, Caroline County, Va.**

ALLEGED VIOLATION: Between 11–28–61 and 12–7–61, *dextro-amphetamine sulfate tablets* (count 1), *tablets containing a mixture of amobarbital and dextro-amphetamine sulfate* (count 2), *dextro-amphetamine sulfate capsules* (count 3), and *amphetamine sulfate tablets* (count 4), were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 3–27–64, the case came on for trial before court and jury and on the same day, the jury returned a verdict of guilty. On 5–1–64, the court sentenced the defendant to 2 years' imprisonment and a $500 fine. On 5–6–64, the defendant filed a notice of appeal. On 10–1–64, the appeal was argued before the United States Court of Appeals for the Fourth Circuit, and on 10–16–64, that court rendered the following opinion (337 F. 2d, 613):

Before HAYNSWORTH, FAHY, and BRYAN, *Circuit Judges.*

PER CURIAM: "Upon four counts of an information a jury found Hubert O. Boyd guilty of dispensing certain toxic drugs without a prescription, after their shipment in interstate commerce, in violation of the Federal Food, Drug, and Cosmetic Act, particularly sections 331(k), 353(b)(1)(B) and 333. On his appeal from the judgment of conviction and sentence, we find the evidence insufficient to justify the verdict on the first three charges inasmuch as it failed to establish that the drugs had been shipped in interstate commerce. Guilt on the fourth count cannot be sustained because toxicity of the drug therein described was not proved. For these reasons we must set aside the judgment and sentence, and remand for entry of a judgment of acquittal.

Reversed and remanded
for final judgment."

8161. (F.D.C. No. 50458. S. No. 64–444 X.)

INFORMATION FILED: 9–9–64, Dist. Minn., against **Emmet P. Darkow, Minneapolis, Minn.**

CHARGE: On 10–26–63, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–11–65. $500 fine, and probation for 2 years.

8162. (F.D.C. No. 50611. S. Nos. 55–662 X, 55–664/6 X, 34–286 A.)

INFORMATION FILED: 11–24–64, E. Dist. Ky., against **Earl M. Britenburg, M.D., Dayton, Ky.**

CHARGE: Between 12–19–63 and 1–16–64, *desoxyephedrine hydrochloride tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–8–65. $500 fine, plus costs.

8163. (F.D.C. No. 50381. S. Nos. 30–720 A, 30–781/2 A.)

INFORMATION FILED: 9–8–64, S. Dist. Ohio, against **Noah Jenkins, t/a Kentucky Truck Stop, Waverly, Ohio, and George Childers.**

CHARGE: Between 1–8–64 and 1–15–64, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Jenkins to 3 counts; guilty by Childers to 1 count.

DISPOSITION: 12–8–64. Jenkins—imprisonment for 3 months; Childers—imprisonment for 60 days.

8164. (F.D.C. No. 49189. S. No. 45–551 V.)

INFORMATION FILED: 4–3–64, W. Dist. Mo., against **Floyd Havener, Springfield, Mo.**

CHARGE: On 1–8–63, *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–23–64. Imprisonment for 3 months.

8165. (F.D.C. No. 50488. S. Nos. 45–255 V, 45–257/60 V, 46–618/19 X, 47–109 X.)

INFORMATION FILED: 10–28–64, E. Dist. Ark., against **Herschel Eagle, Stuttgart, Ark.**

CHARGE: Between 3–5–63 and 8–27–63, *desoxyephedrine hydrochloride tablets* were dispensed 5 times, *dextro-amphetamine phosphate tablets* were dispensed twice, and *amphetamine sulfate tablets* and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–9–64. $200 fine, and probation for 1 year.

8166. (F.D.C. No. 50021. S. Nos. 15–038 X, 17–406 X, 17–408/13 X.)

INFORMATION FILED: 7–2–64, S. Dist. Ohio, against **Robert H. Dooley, t/a Dooley's Pharmacy No. 1, Dayton, Ohio, and Leonard A. Zimmerman (pharmacist).**

CHARGE: Between 8–14–63 and 10–17–63, *Dexedrine Sulfate tablets* were dispensed 5 times and *Tuinal capsules* were dispensed 3 times, upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty by Dooley to 1 count; by Zimmerman to 7 counts.

DISPOSITION: 2–19–65. Dooley—$900 fine; Zimmerman—sentence suspended.

8167. (F.D.C. No. 50355. S. Nos. 59–573 V, 59–575 V, 59–596 V.)

INFORMATION FILED: 8–10–64, N. Dist. Ga., against **Mack L. Glover, Alpharetta, Ga.**

CHARGE: Between 3–29–63 and 5–9–63, *Dexedrine Sulfate tablets* were dispensed twice and *Dexamyl tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1–27–65. $100 fine, and probation for 2 years.

8168. (F.D.C. No. 50610. S. Nos. 15–707 X, 15–710 X, 15–714 X, 32–701 A.)

INFORMATION FILED: 11–24–64, S. Dist. Ohio, against **Robert Kattman, t/a Kattman Pharmacy, Cleves, Ohio.**

CHARGE: Between 12–17–63 and 1–7–64, *Diuril tablets* were dispensed 3 times and *Sulfadiazine tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–17–64. $200 fine.

8169. (F.D.C. No. 50013. S. Nos. 6–549 V, 6–551 V, 6–555 V, 8–745/7 V, 56–205 V.)

INFORMATION FILED: 6–5–64, Dist. Mass., against **Kelley Square Drug Co., Inc., t/a White's Drug, Worchester, Mass., and Charlotte White (treasurer).**

CHARGE: Between 3–11–63 and 4–25–63, *Doriden tablets* were dispensed 3 times and *penicillin G potassium tablets* were dispensed once without a prescription; and *meprobamate tablets*, *Miltown tablets*, and *Equanil tablets* were each dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–19–64. Each defendant fined $100.

8170. (F.D.C. No. 49868. S. Nos. 29–653 X, 29–656 X, 29–658 X, 29–689 X.)

INFORMATION FILED: 5–5–64, Dist, Nebr., against **John C. Skomal, t/a Brown Park Pharmacy, Omaha, Nebr.**

CHARGE: Between 9–3–63 and 9–27–63, *Benzedrine Sulfate tablets* and *Tuinal capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–23–64. $100 fine, plus costs.

8171. (F.D.C. No. 45547. S. Nos. 104–821/2 A.)

PETITION FILED: 8–17–64, W. Dist. Wash., against **Alfred M. Holland (pharmacist), Aberdeen, Wash.,** to answer for alleged violation of probation. (See Drug and Device Notice of Judgment No. 6639.)

ALLEGED VIOLATION: Between 6–29–64 and 6–30–64, *Benzedrine Sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8–24–64. $1,000 fine, and probation for 2 additional years.

8172. (F.D.C. No. 50165. S. Nos. 62–224/25 V, 62–242 V.)

INFORMATION FILED: 8–27–64, S. Dist Calif., against **North Palos Drug Corp., Lomita, Calif., William M. Arenstein (pharmacist and president), and Harriet F. Ursem (pharmacist).**

CHARGE: Between 6–4–63 and 7–12–63, *Equanil tablets* were dispensed twice and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation to 3 counts, by William A. Arenstein to the count involving *Dexedrine Sulfate tablets*, and by Harriet F. Ursem to 1 count involving *Equanil tablets*.

DISPOSITION: 11–3–64. Corporation—$900 fine; each individual—probation for 4 years.

8173. (F.D.C. No. 50342. S. Nos. 15–207 X, 15–222 X, 15–230 X.)

INFORMATION FILED: 9–11–64, S. Dist. Ohio, against **Lester E. Held, t/a Held's Madison Avenue Pharmacy, Springfield, Ohio, and Duane L. Twait (pharmacist).**

CHARGE: Between 7–22–63 and 7–31–63, *Equanil tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Held to 3 counts; by Twait to 1 count.

DISPOSITION: 2–19–65. Held—$400 fine; Twait—sentence suspended.

8174. (F.D.C. No. 50169. S. Nos. 15–190 X, 15–199 X, 15–212 X, 15–221 X, 15–237 X, 17–049 X, 17–055 X.)

INFORMATION FILED: 7–2–64, S. Dist. Ohio, against **Rollin E. Ballentine, t/a Higgins Pharmacy, New Carlisle, Ohio.**

CHARGE: Between 7–12–63 and 8–9–63. *Equanil tablets* were dispensed 5 times and *Dexedrine Sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 2–19–65. $700 fine.

8175. (F.D.C. No. 50380. S. Nos. 15–087/93 X.)

INFORMATION FILED: 8–31–64, E. Dist. Ky., against **Charles E. Skaggs, t/a The Lawrence Drug Store, Louisa, Ky.**

CHARGE: Between 12–18–63 and 12–20–63, *Librium Hydrochloride capsules* were dispensed 3 times, *penicillin tablets* were dispensed 3 times, and *thyroid tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–8–64. $2,800 fine, plus costs, imprisonment for 1 year and 1 day suspended, and probation for 2 years.

8176. (F.D.C. No. 50364. S. Nos. 15–991 X, 55–483/5 X.)

INFORMATION FILED: 8–31–64, S. Dist. Ohio, against **Nathan Drucker, t/a Drucker Drugs, Cincinnati, Ohio, and Charles A. Gilford (pharmacist).**

CHARGE: Between 9–27–63 and 10–3–63, *Librium Hydrochloride capsules* were dispensed twice and *prednisone tablets* and *phenobarbital tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–8–64. Drucker—$300 fine, 6 months in prison suspended, and probation for 6 months; Gilford—$200 fine, 6 months in prison suspended, and probation for 6 months.

8177. (F.D.C. No. 49864. S. Nos. 20–928 V, 20–930/1 V.)

INFORMATION FILED: 8–10–64, S. Dist. Tex., against **Kuo Chuan William Huang (pharmacist), Port Isabel, Tex.**

CHARGE: Between 5–20–63 and 5–22–63, *penicillin tablets* were dispensed twice, and *meprobamate tablets* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 8–24–64. $50 fine.

8178. (F.D.C. No. 49863. S. Nos. 15–301/4 X, 17–821 X, 17–824/30 X.)

INFORMATION FILED: 5–14–64, W. Dist. Ky., against **Mrs. Edna F. Friedman, t/a Martin's Pharmacy, Louisville, Ky., and Arthur Kreitman (pharmacist).**

CHARGE: Between 6–6–63 and 7–26–63, *Seconal Sodium capsules*, *Dexedrine Sulfate tablets*, and *Butazolidin tablets* were each dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–5–64. Each defendant fined $300.

8179. (F.D.C. No. 50479. S. Nos. 78–985 A, 78–992/3 A.)

INFORMATION FILED: 9–14–64, Dist. N.J., against **Charles R. Rothenberg, t/a Hollywood Pharmacy, Orange, N.J.**

CHARGE: Between 6–2–64 and 6–10–64, *Seconal Sodium capsules* were dispensed twice and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–9–64. Sentence of 1 year in prison suspended, and probation for 1 year.

8180. (F.D.C. No. 50023. S. Nos. 341 X, 2–087 X, 65–405/6 X, 84–281/2 X.)

INFORMATION FILED: 6–3–64, S. Dist. Ga., against **Williamson's Pharmacy, Inc., Savannah, Ga., and Tom F. Williamson (president-pharmacist).**

CHARGE: Between 9–28–63 and 11–13–63, *Thorazine tablets* were dispensed 3 times and *Achromycin capsules*, *Doriden tablets*, and *Miltown tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–6–64. $5,000 fine, and probation for 5 years against defendants jointly.

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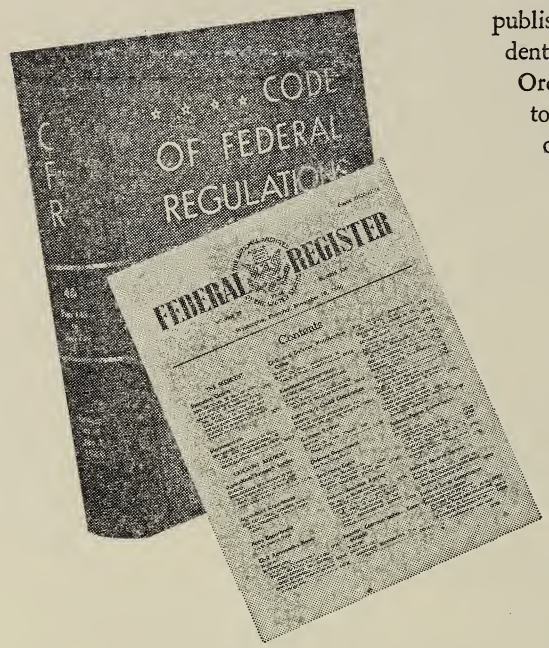

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D.D.N.J., F.D.C. 8181–8240 Issued December 1965

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8181–8240

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default, consent, or, in one case, a court opinion on a question of law. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *December 17, 1965.*

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* For presence of a habit-forming substance without warning statement, see No. 8193; omission of, or unsatisfactory, ingredients statements, Nos. 8193, 8193; failure to bear a label containing an accurate statement of the quantity of the contents, No. 8193; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 8214; cosmetics actionable under the drug provisions of the Act, Nos. 8234, 8235.

793-569—65——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J., NOS. 8181–8240

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading: Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man, and it contained a quantity of the narcotic or hypnotic substance, peyote, and its label failed to bear the name, and quantity or proportion of such substance and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(e)(1)(A)(i), the article was a drug, and its label failed to bear the established name of the drug; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an approval of an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8181. Sterile estrone injection. (F.D.C. No. 50718. S. No. 53–510 A.)

QUANTITY: 294 individually ctnd. vials at Detroit, Mich., in possession of Fellows-Testagar, Div. of Fellows Medical Manufacturing Co., Inc.

SHIPPED: 9–5–61 and 6–29–62, from Indianapolis, Ind., and Ontario, Calif.

LABEL IN PART: (Ctn. and vial) "10 cc Vial No. * * * Sterile—Estrone—2 Mg. Per cc.—Fellows-Testagar Div. of Fellows Medical Mfg. Co., Inc. Detroit, Mich."

RESULTS OF INVESTIGATION: The article was manufactured from raw ingredients, namely, Merthiolate powder and pectin, which had been shipped as described above. Examination showed that the article contained bacteria.

LIBELED: 10–13–64, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the label statement "Sterile—Estrone—" was false and misleading as applied to a product containing bacteria; and 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling, due to the presence of bacteria.

DISPOSITION: 12–2–64. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

8182. Mucorhicin, Pangamic Acid Salt Solution, Wobe enzymes, Regeneresen. (F.D.C. No. 49958. S. Nos. 80–501/4 A, 80–507/12 A.)

QUANTITY: 27 btls. of *Mucorhicin*; 5 vials, each containing 30 cc. of *Pangamic Acid Salt Solution*; 21 ampuls of *Wobe enzymes*; and 162 ctns. containing 580 ampuls of *Regeneresen*, at Brewster, N.Y.

SHIPPED: (*Mucorhicin*) 8–12–63, from Pittsburgh, Pa., by Joseph W. Wilson, M.D.; (*Pangamic Acid Salt Solution*) 1–22–62, from San Francisco, Calif., by Krebs Laboratories; (*Wobe enzymes*) 1961 from Vienna, Austria by Sanabo; (*Regeneresen*) and on unknown dates, from Germany, by C. H. Buer, Koln—Braunsfeld.

LABEL IN PART: (Btl.) "Mucorhicin * * * Joseph W. Wilson, M.D. * * * Pittsburgh 24, Pa."; (vial) "30 cc. solution of Pangamic Acid Salt * * * Pangamic Acid Sodium 35 mg. to the cc. * * * Krebs Laboratories * * * San Francisco 10, Calif."; (ampul) "2131 Wobe '2' Enzymes," "0321 Wobe Enzymes 50 mg."; and (ctn.) "Regeneresen 5 Ampullen C. H. Buer Koln—Braunsfeld."

LIBELED: 4–6–64, S. Dist. N.Y.

CHARGE: 505(a)—when shipped, the articles were new drugs which may not be introduced into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drugs.

DISPOSITION: 4–24–64. Default—destruction.

8183. Pentaerythritol tetranitrate capsules. (F.D.C. No. 49801. S. No. 51–315 A.)

QUANTITY: 7 37,500-capsule drums at St. Louis, Mo.

SHIPPED: 2–11–64, from Detroit, Mich., by S. J. Tutag & Co.

LABEL IN PART: (Drum) "Pentaerythritol Tetranitrate 80—Each Capsule Contains—80 Mg.—Each Capsule So Prepared That The Drugs Are Released Over A Period Of Approximately 6 To 10 Hours."

LIBELED: 2–19–64, E. Dist. Mo.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 4–24–64. Default—destruction.

8184. Nyscap capsules. (F.D.C. No. 49992. S. No. 7–116 A.)

QUANTITY: 1 drum of approximately 200,000 capsules at Washington, D.C.

SHIPPED: 1–27–64, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Drum) "Special Formula * * * Nyscaps * * * Each Nyscap contains: DL Desoxyephedrine HCl 30 mgm. Butabarbital 5/6 gr. Aloin 5/6 gr. Warning * * * Caution * * * Manufactured by Nysco Laboratories, Inc. Long Island City, New York."

LIBELED: 4–21–64, Dist. Columbia.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 6–19–64. Default—destruction.

8185. **Phenylpropanolamine hydrochloride capsules.** (F.D.C. No. 50308. S. No. 62–834 A.)

QUANTITY: 384 30-capsule pkgs. at Huntington Park, Calif.

SHIPPED: 4–29–64, from Philadelphia, Pa., by Vitamix Pharmaceuticals, Inc.

LABEL IN PART: (Pkg.) "30–Day Supply SLIM-EASY * * * An aid for reducing * * * One Capsule, Once Daily * * * Each capsule contains as active ingredients. Phenylpropanolamine Hydrochloride 75 mg. * * * Distributed by Daylin Drugs, Inc. Huntington Park, Calif."

ACCOMPANYING LABELING: Package insert entitled "Eat what you like, but * * *."

RESULTS OF INVESTIGATION: The article had been manufactured by Vitamix Pharmaceuticals, Inc., Philadelphia, Pa., and shipped in bulk, as described above, to Riders, Ltd., Saugus, Calif., which firm repacked the article and delivered it to Daylin Drugs, Inc.

LIBELED: 6–23–64, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article and the name, "Slim-Easy," contained false and misleading representations that the article was adequate and effective as an aid for reducing; that one might eat what one likes but lose weight the comfortable way; that the article would supply extra pep and energy and assist in relieving the low-down, depressed feeling one usually has on a diet; and that one would feel better all day the easy way; and 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since no approval of a application filed pursuant to 505(b) was effective with respect to such article.

DISPOSITION: 7–22–64. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

8186. **Ferromax peptonized iron.** (F.D.C. No. 50070. S. No. 60–497 A.)

QUANTITY: 166 30-cc. vials at Los Angeles, Calif.

SHIPPED: 1–11–64, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: "Ferromax Peptonized Iron 100 mg/cc Elemental Iron 18 mg/cc * * * Wholesale Distributors B&B Laboratories, Los Angeles 6, Calif."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 78.5 percent of the declared amount of iron.

LIBELED: 4–30–64, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Peptonized Iron 100 mg/cc Elemental Iron 18 mg/cc" was false and misleading; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was subject to the provisions of 503(b)(1), and its

label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5–22–64. Default—destruction.

8187. **Facto-B vitamin tablets.** (F.D.C. No. 49943. S. Nos. 49–873/4 A.)

QUANTITY: 13 21-tablet btls. and 164 100-tablet btls. at Detroit, Mich., in possession of Linblad's, Inc.

SHIPPED: 11–6–63 and 12–11–63, from Cedar Rapids, Iowa.

LABEL IN PART: (Btl.) "Facto-B Made from * * * and other Lipotrophic Factors from food sources Each Tablet Contains * * * Liver-Stomach Concentrate (contains Intrinsic Factor) 130 Mg. * * * Iron (Ferrous Fumarate) 110 Mg. [MDR] 200% * * * Vitamin B_2 7.5 Mg. [MDR] 375% * * * Folic Acid 0.15 Mg. * * * Directions Use one tablet per meal."

RESULTS OF INVESTIGATION: The articles had been repacked by the dealer into bottles from bulk tablets shipped as above.

LIBELED: 3–27–64, E. Dist. Mich.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use of the article as a lipotropic factor which it was represented to be; and 503(b)(4)—the article was subject to the requirements of 503(b)(1) because of the presence therein of intrinsic factor, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 5–14–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

8188. **Amphetamine tablets.** (F.D.C. No. 50212. S. Nos. 86–124/5 A.)

QUANTITY: Approximately 600,000 tablets at E. Peoria, Ill., in possession of Andrew J. Persich.

SHIPPED: Prior to 5–25–64, from outside the State of Illinois.

LIBELED: 5–25–64, S. Dist. Ill.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since the possessor was not regularly and lawfully engaged in dealing in prescription drugs.

DISPOSITION: 9–8–64. Default—delivered to the Government.

8189. **Amphetamine sulfate tablets.** (F.D.C. No. 49922. S. Nos. 56–602/4 A.)

QUANTITY: 50,000 tablets at Des Moines, Iowa, in possession of William L. Pennington.

SHIPPED: Prior to 3–19–64, from outside the State of Iowa.

LIBELED: 3–19–64, S. Dist. Iowa.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such

*See also Nos. 8186, 8187.

requirement since it was a prescription drug which was not in the possession of a person who was regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since it was not to be dispensed upon prescription as required by 503(b).

DISPOSITION: 8–24–64. Default— destruction.

8190. Amphetamine sulfate tablets. (F.D.C. No. 49787. S. No. 56–449 A.)

QUANTITY: 25,000 tablets at Newton, Kans., in possession of Kenneth E. Wiemerslage, D.C.

SHIPPED: On unknown dates, from outside the State of Kansas.

LIBELED: On or about 5–5–64, Dist. Kans.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since it was in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since the article was not to be dispensed upon prescription.

DISPOSITION: 8–31–64. Default—300 tablets delivered to the Food and Drug Administration; remainder destroyed.

8191. Progesterone tablets. (F.D.C. No. 49966. S. No. 39–215 A.)

QUANTITY: 3,500 tablets in a bulk drum and in repacked ctns., at Dallas, Tex., in possession of Ryan Laboratories.

SHIPPED: 4–22–60, from Cincinnati, Ohio.

LABEL IN PART: (Ctn.) "Each Tablet Contains: Progesterone 10 Mg."

RESULTS OF INVESTIGATION: The article was shipped in bulk as above and was repacked from bulk, by the dealer, into cartons.

LIBELED: On or about 5–29–64, N. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since its labeling failed to conform to the requirement of regulations, namely, that the article's labeling bear adequate information for its use under which practitioners licensed by law to administer such drug can use the drug safely and for the purposes for which it was intended.

DISPOSITION: 8–24–64. Default—destruction.

8192. Beseglan multiglands extract injection. (F.D.C. No. 50305. S. Nos. 79–975/6 A, 80–433 A.)

QUANTITY: 885 30-cc. vials of *Beseglan Plus* and 497 30-cc. vials of *Beseglan*, at Brooklyn, N.Y.

SHIPPED: Between 4–20–64 and 6–10–64, from Pennsauken, N.J., by Generic Drugs, Inc.

LABEL IN PART: (Vial) "Beseglan [or 'Beseglan Plus'] Multiglands Extract Injection Caution * * * Distributed by Paramount Surgical Supply Company Brooklyn, N.Y."

ACCOMPANYING LABELING: Package inserts entitled "Multiglands Extract Injection * * * for a non-specific protein therapy."

LIBELED: 6–23–64, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for nonspecific protein therapy; and 502(f)(1)—the labeling failed to bear adequate directions for use since the articles were worthless for any therapeutic purpose and no adequate directions for their use could be written.

DISPOSITION: 7–28–64. Default—destruction.

8193. Peyote buttons. (F.D.C. No. 50142. S. No. 1–978 A.)

QUANTITY: 1 box containing approximately 100 peyote buttons at Miami, Fla.

SHIPPED: 2–20–64, from Laredo, Tex., by Moore's Orchids.

LABEL IN PART: (Box) "Moore's Orchids * * * Laredo, Texas * * * Orchid Plants Perishable."

LIBELED: On or about 6–9–64, S. Dist. Fla.

CHARGE: 502(b)(2)—when shipped, the article failed to bear a label containing an accurate statement of the quantity of contents; 502(d)—the article contained the substance, peyote, and its label failed to bear the name and quantity or proportion of such substance and, in juxtaposition therewith, the statement "Warning—may be habit forming"; 502(e)(1)(A)(i)—the label failed to bear the established name of the drug, namely, peyote; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was of such nature that it was not possible to write adequate directions for safe and efficacious use by the layman.

DISPOSITION: 7–27–64. Default—destruction.

8194. Dicyl capsules. (F.D.C. No. 50399. S. No. 31–180 A.)

QUANTITY: 12 unlabeled 1,000-capsule btls. at Lexington, Ky., in possession of Tully Laboratories, Inc.

SHIPPED: 5–6–64, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Ctn.) "Shaw St. Louis * * * #0 Red & Clear Dicyl Capsules Each capsule contains: Salicylamide 240 mg. Dipyrone 240 mg. Caution * * * Dosage * * * Caution: Federal law prohibits * * * Mfg. for Tully Laboratories * * * by Shaw Pharmacal Co. * * * St. Louis 15, Mo."

ACCOMPANYING LABELING: Bottle insert reading in part "Dipyrone Composition * * * Action * * * Indications."

RESULTS OF INVESTIGATION: The article had been shipped in cartons labeled as above and would, in the ordinary course of the dealer's business operations, be labeled in part "Distributed by Tully Laboratories, Inc., Lexington, Kentucky" and accompanied by the bottle insert.

LIBELED: 8–12–64, E. Dist. Ky.

CHARGE: 502(a)—while held for sale, the bottle insert contained statements which represented and suggested that articles containing dipyrone had a wide range of usefulness and were indicated as an analgesic and antipyretic because of the absence of serious untoward effects; that such articles offered prompt relief of pain with a minimum of side effects; and that such articles may be used as a substitute for narcotics without the common side effects and addiction liability of narcotics, which statements were false and misleading as applied to *Dicyl capsules* and to other articles containing dipyrone, since such articles have exhibited serious side effects; and 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for

use and it was not exempt from that requirement, since the article was a prescription drug and its labeling failed to conform to the reqirements of regulations requiring adequate information for use, including indications and any relevant hazards, contraindications, side effects, and precautions, under which licensed practitioners can use the drug safely.

DISPOSITION: 9–23–64. Default—destruction.

8195. Ex-Ess tablets. (F.D.C. No. 48132. S. No. 57–888 T.)

QUANTITY: 3 cases containing a total of approximately 113,000 tablets, and 2 180-tablet btls., at Indianapolis, Ind., in possession of The Garglette Co.

SHIPPED: 2–1–62, from Cincinnati, Ohio.

LABEL IN PART: (Btl.) "Ex-Ess Tablets Neutralize Excess Acid Contains: * * * Manufactured for The Garglette Co. Indianapolis, Ind. * * * Directions."

ACCOMPANYING LABELING: Repack-bottle labels.

RESULTS OF INVESTIGATION: All of the article had been shipped in bulk; the bottles had been repacked by the dealer from bulk tablets; and, in the normal course of the dealer's business operations, all of the article would have been repacked into retail-size bottles.

LIBELED: 10–15–62, S. Dist. Ind.; libel amended on or about 9–20–63.

CHARGE: 502(a)—while held for sale, the labeling of the article, the repack-bottle label, contained false and misleading representations that the article was adequate and effective for use by the laity as a treatment for and preventive of indigestion, gas in stomach, burning urine, headache, protecting the kidneys and teeth of expectant mothers, fatigue due to excess acid, and that colds were made worse by excess acid; that the product was beneficial following overindulgence; and that the product was adequate and effective for treating acute conditions and severe cases; and 502(f)(1)—the article failed to bear adequate directions for use of the article in the dosage and for the conditions and purposes for which it was offered and intended to be used.

DISPOSITION: On 11–9–62, The Garglette Co., by Hilda H. James, claimed the article. On 10–17–63, the Government filed written interrogatories. On 10–25–63, the claimant filed objections to, and a motion to strike, the Government's written interrogatories. On 11–4–63, the claimant served an answer in which they denied that the article was misbranded. On 12–4–63, the court denied the claimant's motion to strike the Government's written interrogatories and ordered that the interrogatories be answered within 15 days. On 2–18–64, The Garglette Co., by Hilda H. James, withdrew their claim and, on 4–2–64, a default decree of condemnation and destruction was entered.

8196. Medtronic exerciser device. (F.D.C. No. 50674. S. Nos. 42–024 A, 42–040 A.)

QUANTITY: 4 devices at Oklahoma City, Okla., in possession of Bertha Hartman, t/a Firm-U-Ette Facial Exercises.

SHIPPED: 5–23–64 and 7–31–64, from Dallas, Tex., by Bioelectronics, Inc., and Medtronics, Inc.

LABEL IN PART: "Medtronic Exerciser."

ACCOMPANYING LABELING: Leaflets entitled "31 Minutes that May Change Your Life Bioelectronics The Scientific Approach to Figure Beauty," "Bioelectronics * * * Your Exercise Program * * * Guarantee Certificate * * *

Mfg. by Bioelectronics, Inc., and "Medtronics * * * Your Exercise Program * * * Guarantee Certificate * * * Manufactured by Medtronics, Inc. * * * Dallas, Texas."

RESULTS OF INVESTIGATION: The article was an electronic muscle stimulator housed in a black, attache-type carrying case with metal fittings. A control panel bore four volume control knobs and three toggle switches. The device, which contained a cord for plugging into an electrial outlet, also contained an attached set of pad electrodes for applying electrical impulses to the body. In use, the device may cause involuntary contractions and relaxation of muscles.

LIBELED: 10–20–64, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for increased metabolism and weight loss; increasing strength, endurance and coordination; increasing joint flexibility; reducing minor aches, pains, stiffness and soreness; correction of remediable postural defects; improvement in appearance; increased efficiency; reduction of chronic fatigue; preventing degenerative disease; preventing the appearances of aging and for facial care and face lifting; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment of weight reduction; back, shoulder, and neck troubles; health; calorie reduction (840 calories in 30 minutes); increasing circulation; and leveling off blood pressure; which were the conditions and purposes for which the article was offered in oral statements made on 8–21–64, by Mrs. Bertha Hartman.

DISPOSITION: 12–8–64. Default—delivered to the Food and Drug Administration.

8197. McKune Whirlpool Bath device. (F.D.C. No. 50596. S. Nos. 69–353 A, 70–862 A.)

QUANTITY: 7 devices at Hopkins, Minn., in possession of Crown Products, Inc.

SHIPPED: 8–20–64 and prior thereto, from Chicago, Ill., by John J. McKune & Sons Co., Inc.

LABEL IN PART: (Front of device) "McKune Whirlpool Bath" and (shipping ctn.) "John J. McKune & Sons Co., Whirlpool Bath Unit * * * Chicago 45, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "Congratulations," "McKune Whirlpool Bath," "Whirlpool Hydro Massage" (for new unit), and "Whirlpool Hydro Massage" (for old unit); placards entitled "Ask For a Room With Whirlpool Massage" and "Tension Stress Nerves on Edge"; and 1 newspaper advertisement headed "Do You Suffer From Arthritis."

RESULTS OF INVESTIGATION: Examination showed that the device was an electric motor which forced air through a plastic tube attached to a perforated metal pipe, which pipe fitted into and around the bottom of a bathtub. The air which was forced through the perforated pipe agitated the water, causing it to become turbulent in order to effect an alleged therapeutic motion.

LIBELED: 10–12–64, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for arthritis, rheumatism, muscular fatigue, tired feet, aching back, insomnia, tension headaches, poor circulation, aches and pains, weight and posture

control, tensions and frustrations, and firming sagging muscles; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment of multiple sclerosis, sciatic nerve trouble, whiplash, and Charley horse, which were the conditions and purposes for which the article was offered in oral statements made on 8–13–64, by Mrs. Irene Rice, representative for Crown Products, Inc., in the presence of a Food and Drug Administration inspector.

DISPOSITION: 11–3–64. Consent—claimed by Crown Products, Inc., for relabeling.

DRUGS FOR VETERINARY USE

8198. **Various veterinary products.** (F.D.C. No. 48835. S. Nos. 33–644 V, 33–646/7 V.)

QUANTITY: 89 unlabeled 2-lb. bags of *Prescription No. H–628*, 94 unlabeled 1-lb. bags of *Prescription No. C–72*, 2 100-lb. drums of *Prescription No. T–157*, at Sleepy Eye, Minn.

SHIPPED: Between 11–16–61 and 6–26–62, from Charles City, Iowa, by Dr. Mayfield Laboratories, Inc.

LABEL IN PART: (Ctn.) "Prescription No. H–628 * * * for prevention of Gut Edema and improved feed conversion * * * for growth stimulation * * * Dr. Mayfield Laboratories, * * * Charles City, Iowa," "Prescription No. C–72 Mastitis * * * mix ten pounds in one ton of dairy feed * * * For individual treatment feed one level teaspoonful per head per day. In severe cases this dose can be doubled for ten days * * * Dr. Mayfield Laboratories * * * Charles City, Iowa," (drum) "Prescription No. T–157 For internal bleeding in turkeys * * * Dr. Mayfield Laboratories, * * * Charles City, Iowa."

LIBELED: 4–4–63, Dist. Minn.; libel amended on or about 11–8–63 and 4–22–64.

CHARGE: 502(e)—when shipped, the labels of the articles failed to bear (1) the common or usual name of the drug, and (2) the common or usual name of each active ingredient; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use.

Prescription No. H–628: 502(a)—the labeling of the article contained false and misleading representations that 2 lbs. of the article added to 1 ton of feed was adequate and effective as a treatment for gut edema and improved feed conversion, and for growth stimulation of pigs up to 5 weeks of age.

Prescription No. C–72: 502(a)—the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for mastitis in dairy cattle.

Prescription No. T–157: 502(a)—the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for all types of internal bleeding in turkeys.

DISPOSITION: The article was claimed by Dr. Mayfield Laboratories, Inc. The Government filed written interrogatories and, after the time for answers had expired, moved for default for failure to answer. The claimant answered the interrogatories on 4–13–64, and also served the Government with written interrogatories. The Government moved to compel further answers, since objections made by the claimant were not timely, and answered claimant's interrogatories.

A hearing was set down before the court on the question raised by the claimant as to whether veterinary drugs may be included under exemption provi-

sions promulgated under 503(b)(2). The court rendered the following pretrial opinion on 9–22–64:

LARSON, *District Judge:* "The above entitled matter was to be tried to the Court on August 29, 1964. Prior to the trial counsel agreed that a question of law should first be disposed of.

"The question is whether veterinary drugs are included in the class of drugs exempted by 21 U.S.C. § 353(b)(2) from the labeling requirements of 21 U.S.C. § 352(f)(1) and (e).

"The Court has considered the briefs of counsel and the files and proceedings herein.

"The action is one brought by the United States to condemn three groups of veterinary drugs which were shipped by the claimant Dr. Mayfield Laboratories, Inc. (Mayfield) from Charles City, Iowa, to the Sleepy Eye Clinic in Sleepy Eye, Minnesota. The Sleepy Eye Clinic was to redistribute the drugs to the ultimate consumers.

"Mayfield admits that the labeling on the drugs did not conform to the requirements of § 502(e) and (f)(1) of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1050–51 (1938), 21 U.S.C. § 352 (1958).[1] However, it claims that the drugs were exempted from those requirements by the provisions of 21 U.S.C. § 353(b)(2).[2]

"The current form of 21 U.S.C. § 353(b) constitutes the major portion of what is often termed the Durham-Humphrey Amendment. It was entered in 1951 and was a substantial change from prior law.[3]

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[1] 52 Stat. 1051–52 (1938) was, at all times here relevant, 21 U.S.C. § 352(a) and provided that a drug was misbranded if it "is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient . . . ."

21 U.S.C. § 352(f) provides that a drug shall be deemed misbranded "unless its labeling bears (1) adequate directions for use. . . ."

[2] 21 U.S.C. § 353(b)(1958), 65 Stat. 648 (1951) provides in part that:
"(b)(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies; or
(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing, and filed by the pharmacist. The Act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.
(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a) (i) (2) and (3), (k), and (l) of said section . . . if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection."

The first of the three lots seized was shipped at a time when the statute used the word "effective" in place of the word "approved" in paragraph (1)(C), but the change has no bearing on the issues here.

[3] Prior to 1951 § 303(b) of the Food, Drug, and Cosmetic Act, 52 Stat. 1052, was designated as 21 U.S.C. § 353(b), and it provided that:

> A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—
>
> (1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and
>
> (2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,
>
> be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502(d).

"The United States claims that in view of the legislative history of the Durham-Humphrey Amendment, paragraph (2) cannot be considered to grant an exemption for veterinary drugs even though all the requirements of that paragraph are met.[4] More specifically, the words 'any drug' should be taken to include only any drug for which a prescription is required under paragraph (1).

"Mayfield argues that the word 'drug' in paragraph (2) is intended to be coextensive with the broad definition of that term given in 21 U.S.C. § 321(g)[5] and supports this reading with the following reasoning.

"One purpose of the Durham-Humphrey Amendment was to ease the restrictions on the sale of veterinary drugs by excluding them from the classes of drugs for which prescriptions are required. Therefore Congress cannot have intended the sale of veterinary drugs to be more severely regulated in any respect after the Amendment than was the case under prior law. But this will be the result if veterinary drugs may not qualify for the exemptions of 21 U.S.C. § 353(b)(2). Since the 1951 Amendment veterinary drugs dispensed on a prescription must carry labeling which conforms to the requirements of 21 U.S.C. § 352, while prior to the Amendment such drugs would have been exempt from those requirements.

"Although there is some merit in the reasoning behind this argument, a full reading of the legislative history has convinced me that the Government's contention should prevail.

"The Senate Report on the Durham-Humphrey Amendment stated that:

SECTIONAL ANALYSIS

Prescription drugs –

'Under paragraph (1) of the new subsection (b) prescription drugs are defined as drugs intended for use by man which fall within any one of three different categories. In limiting prescription drugs to those intended for use by man this subsection differs from the present law, which refers to prescription drugs to include not only those dispensed on prescription of physicians and dentists, but also those dispensed on prescription of a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under section 502(f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian. In the absence of any exempting regulations, these drugs will be subject to the labeling and dispensing requirements of the act applicable to over-the-counter drugs.

Labeling of prescription drugs –

'Paragraph (2) of the new subsection (b) provides that a drug dispensed on prescription shall be exempt . . . (from certain parts of 21 U.S.C. § 352.)'[6]

"The committee report alone would seem to virtually require the conclusion that all the paragraphs of 21 U.S.C. § 353(b) are only meant to deal with the category of prescription drugs defined in paragraph (1). Mayfield tries to avoid the thrust of this language by suggesting that most of it is directed only at 21 U.S.C. § 353(b)(1). This distinction seems impossible.

"The Senate Report carefully distinguishes throughout whether it is talking about subsection (b) or merely a paragraph of the subsection. Thus it appears to the Court that the second sentence quoted must be interpreted as applying to subsection (b) as a whole and indicating that all of its provisions only apply to the prescription drugs defined in paragraph (1).

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[4] There is a substantial question in this case as to whether Mayfield could meet the conditions of 21 U.S.C. § 353(b)(2), but that point has not been argued by the parties, and for the purposes of this decision it is assumed that Mayfield may claim the exemptions of that section if it may be applied to veterinary drugs.

[5] 21 U.S.C. § 321(g) (1958), 52 Stat. 1041 (1938), provides that:

> The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or the official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3) of this paragraph; but does not include devices or their components, parts, or accessories.

[6] S. Rep. No. 946, 82d Cong. 1st Sess. (1951), reprinted in 1951 U.S. Code Cong. & Ad. News 2454, 2461–62.

"In any event, the rest of the paragraph clearly indicates that veterinary drugs will not be exempt under 21 U.S.C. § 353(b)(2) even though they are to be used by or under the supervision of a veterinarian. While the Report does not specifically mention the possibility that the veterinarian may have issued a prescription for the drug, that idea would seem to have been included within the language.

"Furthermore, it would be anomalous to read the report as saying that even though a prescription is no longer required for the dispensing of veterinary drugs, the use of a prescription in dispensing such drugs will entitle the drugs to the exemptions of 21 U.S.C. § 353(b)(2). The main purpose of prescriptions under 21 U.S.C. § 353(b)(1) is obviously to authorize the pharmacist to issue the drugs to the patient. That would not be the purpose of a prescription for veterinary drugs. Such a prescription would only indicate that a veterinarian was supervising the use of the drugs. Yet this is exactly the type of situation which the Report clearly states is to be governed by regulations. To give effect to a prescription which is not required under 21 U.S.C. § 353(b)(2) would merely permit doing under the statute what the Report specifically contemplates is to be governed by regulations.

"The Court is strengthened in this interpretation by the fact that nowhere in the hearings on the Durham-Humphrey Amendment did anyone indicate that paragraph (2) of the Amendment might be available to exempt over-the-counter drugs. All the comments on paragraph (2) only deal with its application to the drugs defined in paragraph (1), which suggests that this was considered to be the limit of its applicability.[7]

"Nor does there appear to be anything unreasonable about this interpretation of the statute. Mayfield urges that the recipient of the drugs is fully protected from harmful effects by the fact that a veterinarian is advising and supervising the use of the drugs. Even assuming that this is so, the information required by 21 U.S.C. § 352(e) would still seem to be of substantial benefit to the purchaser of the drugs.

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[7] The testimony of Charles Dunn, counsel for the American Pharmaceutical Manufacturers' Ass'n, is typical. He characterized the bill as follows:

> "The first comment is that this bill has four significant purposes . . . .
>
> "The first purpose is to make the prescription-drug law of the FDC Act a truly adequate protection of the public health, by duly restricting the retail dispensing of dangerous drugs to a prescription basis.
>
> "The second purpose is to consolidate the entire prescription-drug law of this act in section 503(b), whereby it is a wholly statutory as distinguished from an administrative law, and a comprehensive positive law.
>
> "The third purpose is to liberalize the existing prescription-drug law of this act, whereby it appropriately permits oral (in addition to written) prescriptions that are promptly reduced to writing and filed by the pharmacist; *and also whereby a prescription drug dispensed in compliance with this law is appropriately exempted from additional label and labeling and packaging requirements in section 502* . . . .
>
> "The fourth purpose of this House bill in its revised form is to strengthen the existing prescription-drug law of this act—and this is the major purpose of the bill—in section 503(b), whereby it appropriately prohibits any unauthorized refilling (as well as filling) of a prescription by a retail druggist; and also whereby the conditions for exempting a prescription drug from the above requirements in section 502 are duly broadened . . . .
>
> "But we should go on to note here, simply for the information of the subcommittee, that on the other hand *H.R. 3298 cuts down the existing prescription-drug law of the FDC Act, by eliminating its application to animal . . . drugs which are prescribed by a veterinarian.*" (Emphasis added.)

Hearings on S. 1186 and H.R. 3298 Before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, 82d Cong. 1st Sess. 105–106 (1951). The same material is reprinted in somewhat different form in 6 Food Drug Cosm. L.J. 420, 426–27 (1951).

A few months after the passage of the Durham-Humphrey Amendment, Mr. Dunn commented:

> The new law is added to Section 503(b) of the FDC Act . . . . It applies to the unsafe drugs made subject thereto, which are introduced into interstate commerce for human use . . . Consequently it does not apply to unsafe animal drugs and therapeutic devices. Their prescription control will be maintained as heretofore by regulations . . . Such a divided prescription state of the FDC Act is a formal defect in it; and that is especially true in the case of unsafe devices for human use. *The New Prescription Drug Law,* 6 Food Drug Cosm. L.J. 951 (1951).

This clearly reflects the belief of a man who had great experience in legislation affecting the drug industry that veterinary drugs could not qualify for the prescription exemption of 21 U.S.C. § 353 (b)(2).

"Since Congress has decreed that these drugs may be freely sold without a prescription, the customer will be able to buy the drug at places which may provide faster delivery or lower prices or be more convenient if he knows the name or ingredients of the drug. That would obviously be impossible here where the only information on the label which referred to the ingredients of the drug enclosed were the terms 'Prescription No. H–528,' 'Prescription No. C–72' and 'Prescription No. T–157.'[8] At the same time the burden on Mayfield of printing new labels for use on these drugs in the future seems very small.

"The answer to the question presented is 'No'. There is no exception."

Thereafter, Dr. Mayfield Laboratories, Inc., withdrew its claim and answer and a decree of condemnation ordering destruction of the drugs was entered on 11–30–64.

8199. Vita Zest medicated premix. (F.D.C. No. 50105. S. Nos. 71–477 A, 71–480 A.)

QUANTITY: 10 5–lb. cans and 27 2½-lb. cans at Blooming Prairie, Minn.

SHIPPED: Between 1–30–64 and 3–16–64, from Wessington Springs, S. Dak., by Vita Zest Corp.

LABEL IN PART: (Can) "Vita Zest Oxytetracycline (Terramycin) 3.2 grams per pound * * * Manufactured by Vita Zest Corporation Wessington Springs South Dakota * * * Poultry Sick Chickens–Chronic respiratory disease (air sac), Blue comb (non-specific enteritis), use 2 tablespoonsful to 1 gallon of drinking water for 4 days or mix 1 lb. of Vita Zest to 100 lbs. feed for 10 days * * * Swine For Bacterial enteritis (necro) (scours) use 2 tablespoonsful to 1 gallon of drinking water, slop or milk for 4 days, then 2 tablespoonsful to 8 gallons of water for 10 days. Use 1 lb. to 100 lbs. of feed for 10 days."

LIBELED: 5–5–64, Dist. Minn.; libel amended 6–30–64.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use in that the directions did not provide adequate and effective levels of the active drug ingredient, oxytetracycline, for the treatment of bacterial enteritis in swine, and chronic respiratory disease and blue comb in sick chickens.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–24–64. Default—destruction.

[8] The benefit to the public from requiring compliance with 352(f)(1) is not so clear in this particular type of case because of 21 C.F.R. § 1.106(f) (1964) which provides that:

Retail exemption for veterinary drugs and prescription devices.

A drug or device subject to paragraph (c) or (d) of this section shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

Although Mayfield would evidently be barred from claiming the protection of this regulation because the shipment was not directed to the ultimate consumer, most prescription sales of veterinary drugs would be exempted from (f)(1) by this provision.

The regulation was promulgated on December 20, 1955. Obviously it indicates a continuous administrative interpretation that the provisions of 21 U.S.C. § 353(b)(2) do not apply to sales of veterinary drugs on prescription. This further reinforces the Court's decision.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

8200. Span-RD capsules. (F.D.C. No. 50585. S. No. 41–161 A.)

QUANTITY: 7 drums of 25,000 capsules each, and 208 100-capsule btls., at Houston, Tex., in possession of Metro Med, Inc.

SHIPPED: 6–25–64 and 6–30–64, from New York, N.Y., by Davis-Edwards Pharmacal Corp.

LABEL IN PART: (Drum) "Davis-Edwards Pharmacal Corporation * * * New York 55, N.Y. Prepared for: Metro Med * * * Span RD TDC Green/Clear * * * Each Capsule Contains: D–Methamphetamine HCl 12 mg. dl-Methamphetamine HCl 6 mg. Butabarbital 30 mg. * * * Caution: Federal law prohibits * * * Dose"; and (btl.) "Span–RD Methamphetamine HCl & Butabarbital Each sustained release capsule contains * * * Metro Med, Inc. Houston, Texas."

ACCOMPANYING LABELING: Package insert entitled "Span-RD (Methamphetamine HCl & Butabarbital) Description of product * * * Composition * * * Indications * * * Side Effects and Precautions."

RESULTS OF INVESTIGATION: Analysis showed that as much as 68.14 percent of methamphetamine hydrochloride present was released in one hour and that not more than 5.4 percent of butabarbital was released in two hours.

The article was shipped in bulk drums as described above and, thereafter, a portion was repacked into bottles by Metro Med, Inc.

LIBELED: 9–22–64, S. Dist. Tex.

CHARGE: 501(c)—when shipped and while held for sale, the quality of the article fell below that which it was purported to possess, since it failed to disintegrate properly; and 502(a)—the accompanying labeling contained false and misleading representations that the medication was released quickly in a therapeutic dose followed by sustained maintenance release for 8 to 10 hours "to provide maximum anorexia effect with relief of symptoms of mental and emotional distress."

DISPOSITION: 11–4–64. Default—destruction.

8201. Progesterone suspension. (F.D.C. No. 50159. S. Nos. 78–255 X, 97–545 A.)

QUANTITY: 5 boxes, each containing 5 1-cc. vials, and 33 boxes, each containing 25 1-cc. vials, at San Francisco, Calif., in possession of Invenex Pharmaceuticals.

SHIPPED: 8–27–63, from New York, N.Y.

LABEL IN PART: (Vial) "Progesterone Suspension NF 50 MG per cc See Insert * * * For Intramuscular Injection Only * * * Invenex San Francisco, California."

RESULTS OF INVESTIGATION: Analysis showed that different vials of the article contained from approximately 76 percent to 170 percent of the declared amount of progesterone. The article had been manufactured by the dealer in part from progesterone shipped as above.

LIBELED: 5–27–64, N. Dist. Calif.

*See also No. 8186.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, "*Progesterone Suspension,*" the name of which was recognized in an official compendium, The National Formulary, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Progesterone Suspension NF 50 MG per cc" was false and misleading as applied to a product which contained more or less than the declared amount of progesterone, and which failed to conform to the standard set by The National Formulary for *progesterone suspension.*

DISPOSITION: 8–18–64. Default—destruction.

8202. Reserpine tablets. (F.D.C. No. 49706. S. No. 7–072 X.)

QUANTITY: 71 ctns., each containing 12 100-tablet btls., and 8 100-tablet btls., at New Haven, Conn.

SHIPPED: Prior to 1–1–59, from Worcester, Mass.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 72 percent of the labeled amout of reserpine alkaloid, namely, 0.25 mg.

LIBELED: 1–13–64, Dist. Conn.

CHARGE: 501(b)—while held for sale, the strength of the article differed from and its quality fell below the standard for "*Reserpine Tablets*" set forth in the United States Pharmacopeia; and 502(a)—the label statement "Each scored tablet contains: Reserpine * * * 0.25 mg." was false and misleading.

DISPOSITION: 7–24–64. Default—destruction.

8203. Litwelfo injection. (F.D.C. No. 49993. S. No. 38–927 A.)

QUANTITY: 214 10-cc. vials at Dallas, Tex.

SHIPPED: 11–12–63, from New Brunswick, N.J., by Smith, Miller & Patch, Inc.

LABEL IN PART: (Vial) "Multiple Dose Vial * * * Litwelfo Each cc contains * * * Folic Acid 5 mg. * * * Intramuscular Smith, Miller & Patch, Inc. New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 70 percent of the declared amount of folic acid.

LIBELED: On or about 5–29–64, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Each cc contains * * * Folic Acid 5 mg." was false and misleading as applied to a product containing less than the declared amount of folic acid.

DISPOSITION: 8–31–64. Default—destruction.

8204. Liver injection and B–12 injection. (F.D.C. No. 50601. S. Nos. 62–841/2 A.)

QUANTITY: 17 cases, each containing 10 individually ctnd. 10-cc. vials of *liver injection,* and 77 individually ctnd. 10-cc. vials of *B–12 injection,* at Whittier, Calif.

SHIPPED: 5–23–62 (*liver injection*) and 3–14–62 (*B–12 injection*), from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analyses showed that the *liver injection* contained approximately 82 percent of the declared amount of folic acid and less than 60 percent of the declared amount of vitamin B_{12}; and the *B–12 injection* contained 30 percent of the declared amount of vitamin B_{12} and less than 50 percent of the declared amount of folic acid.

LIBELED: 9–29–64, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the articles differed from that which they were purported to possess; and 502(a)—the label statements for the *liver injection* "Each cc. contains Vitamin B–12 30 mcg. Folic Acid 5 mg." and for the *B–12 injection* "Each cc. contains * * * B–12 Crystalline 30 mcgms. Folic Acid 5 mgms." were false and misleading as applied to products containing less than the declared amounts of these ingredients.

DISPOSITION: 10–21–64. Default—destruction.

8205 Liver, iron, and vitamins with B_{12} injection. (F.D.C. No. 50556. S. No. 3–297 A.)

QUANTITY: 9 ctns., each containing 10 individually ctnd. 30-cc. vials at Miami Springs, Fla.

SHIPPED: 5–27–64, from Philadelphia, Pa.

LIBELED: 8–26–64, S. Dist. Fla.

CHARGE: 501(c)—while held for sale, the article was not subject to the provisions of 501(b) and its strength fell below that which it purported and was represented to possess, in that each 2 cc. contained less than 5 mcg. of vitamin B_{12}; and 502(a)—the label statement "Vitamin B_{12} Mcg." was false and misleading as applied to a product containing less than the declared amount of this ingredient.

DISPOSITION: 11–18–64. Default—destruction.

8206. Ophthalmic solution. (F.D.C. No. 50072. S. No. 50–599 X.)

QUANTITY: 417 7.5-cc. btls. at San Francisco, Calif., in possession of Broemmel Pharmaceuticals.

SHIPPED: The article was manufactured in part from prednisolone, shipped in January 1963, from East Paterson, N.J.

LABEL IN PART: "Op-Pedrin Sterile Opthalmic Solution Active Ingredients: 0.125 percent Prednisolone O.125 percent Phenylephrine Hydrochloride—Broemmel Pharmaceuticals, San Francisco, California."

RESULTS OF INVESTIGATION: The dealer had manufactured the article in part from prednisolone shipped as above. Analysis showed that the article contained approximately 30 percent of the declared amount of prednisolone.

LIBELED: 5–5–64, N. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "0.125 percent Prednisolone" was false and misleading.

DISPOSITION: 11–19–64. Default—destruction.

8207. Rubber prophylactics. (F.D.C. No. 49920. S. No. 25–154 A.)

QUANTITY: 250 boxes, each containing 72 2-unit pkgs., at Elgin, Ill.

SHIPPED: 11–6–63, from Akron, Ohio, by Allied Latex Sales Co., Inc.

LABEL IN PART: (Pkg.) "Package of Two Royal Knight Nipple End Prophylactics Sold for the Prevention of Disease Only Manufactured for Allied Latex Sales Co. New York 19, N.Y."; (unit) "Liquid Latex Sold For Prevention of Disease Only Made in U.S.A. 0–10–63."

RESULTS OF INVESTIGATION: Examination of 83 prophylactics showed that 2.4 percent contained holes.

LIBELED: 3–13–64, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement (package and unit) "Sold for ["the"] Prevention of Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 4–17–64. Default—destruction.

8208. Rubber prophylactics. (F.D.C. No. 49503. S. Nos. 19–160 X, 19–894 X.)

QUANTITY: 4 cases, each containing 25 ctns. of 48 3-unit vials each, of *Clear-Tone Super Thin Reservoir prophylactics;* and 15 cases, each containing 25 ctns. of 72 2-unit pkgs. each, of *Royal Knight prophylactics*, at Dallas, Tex.

SHIPPED: 10–4–63, from Akron, Ohio, by Allied Latex Sales Co., Inc.

LABEL IN PART: (Vial) "Sold for the Prevention of Disease Only Clear Tone Super Thin Reservoir * * * Manufactured For Allied Latex Sales Co. New York, N.Y."; (pkg.) "Royal Knight Prophylactics Sold for the Prevention of Disease Only * * * Manufactured For Allied Latex Sales Co. New York 19, N.Y."

RESULTS OF INVESTIGATION: Examination showed that 2.5 percent of the "Clear-Tone" units and 1.1 percent of the "Royal Knight" units tested were defective in that they contained holes.

LIBELED: On or about 12–17–63, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the Prevention of Disease Only" was false and misleading.

DISPOSITION: 2–27–64. Default—destruction.

8209. Rubber prophylactics. (F.D.C. No. 49248. S. No. 29–629 X.)

QUANTITY: 140 ctns., each containing 72 2-unit pkgs., at Wichita, Kans.

SHIPPED: 7–10–62 and 6–14–63, from New York, N.Y., by Allied Latex Sales Co.

LABEL IN PART: (Pkg.) "Royal Knight Prophylactics * * * Sold For The Prevention of Disease Only Manufactured For Allied Latex Sales Co. New York 19, N.Y." and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 2.7 percent of the units examined were defective in that they contained holes.

LIBELED: On or about 9–10–63, Dist. Kans.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statements "Sold for ["the"] Prevention of Disease Only" were false and misleading.

DISPOSITION: 12–18–63. Default—destruction.

8210. Rubber prophylactics. (F.D.C. No. 49522. S. No. 1–836 X.)

QUANTITY: 64 ctns., each containing 1,440 individually foil-wrapped units, at Clearwater, Fla.

SHIPPED: 9–20–63, from Newark, N.J., by Allied Latex Sales Co.

LABEL IN PART: (Foil wrapper) "Gold Dollar One Latex Prophylactic Mfd. for Allied Latex Sales Co. Newark, N.J."

RESULTS OF INVESTIGATION: Examination indicated that approximately 0.7 percent of the units examined were defective.

LIBELED: 11–27–63, M. Dist. Fla.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 1–17–64. Default—destruction.

8211. Rubber prophylactics. (F.D.C. No. 49654. S. No. 67–270 X.)

QUANTITY: 266 ctns., each ctn. containing 12 sleeves, each sleeve containing 4 3-unit pkgs., at Norfolk, Va.

SHIPPED: 6–14–63 and 7–24–63, from Memphis, Tenn., by Allied Latex Sales Co., Inc.

LABEL IN PART: (Pkg.) "Gems * * * Manufactured for Allied Latex Sales Co. Inc. N.Y. 5, N.Y. Sold for the Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 1.2 percent of the units examined were defective in that they contained holes.

LIBELED: On or about 12–30–63, E. Dist. Va.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the Prevention of Disease Only" was false and misleading.

DISPOSITION: 1–15–64. Default—destruction.

8212. Rubber prophylactics. (F.D.C. No. 49516. S. No. 64–831 X.)

QUANTITY: 36 cases, containing 12½ gross each, of individually packaged devices, at Durham, N.C.

SHIPPED: 9–25–63, from New York, N.Y., by Allied Latex Sales Co., Inc.

LABEL IN PART: (Pkg.) "Gentry with Genitrol * * * Sold Only For The Prevention of Disease * * * Manufactured for Allied Latex Sales Co., Inc. New York 5, N.Y."

RESULTS OF INVESTIGATION: Examination showed that 0.7 percent of the units examined were defective in that they contained holes.

LIBELED: 11–12–63, M. Dist. N.C.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold Only For The Prevention of Disease" was false and misleading.

DISPOSITION: 2–10–64. Default—destruction.

8213. Rubber prophylactics. (F.D.C. No. 59247. S. No. 20–779 X.)

QUANTITY: 27 boxes, each box containing 25 ctns., each ctn. containing 72 2-unit pkgs., at Dallas, Tex.

SHIPPED: 6–28–63 and 7–17–63, from Memphis, Tenn., by Allied Latex Sales Co., Inc.

LABEL IN PART: (Pkg.) "Gentry with Genitrol * * * Sold Only For The Prevention of Disease * * * Manufactured for Allied Latex Sales Co., Inc. New York 5, N.Y." and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 0.9 percent of the units examined were defective in that they contained holes.

LIBELED: 10–10–63, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statements "Sold Only For The Prevention of Disease" and "Sold For Prevention of Disease Only" were false and misleading.

DISPOSITION: 2–27–64. Default—destruction.

8214. Rubber prophylactics. (F.D.C. No. 49435. S. No. 46–605 X.)

QUANTITY: 19 cases, each containing 25 boxes, each box containing 72 2-unit pkgs., at Hot Springs, Ark.

SHIPPED: 9–18–63, from New York, N.Y., by Allied Latex Sales Co., Inc.

LABEL IN PART: (Pkg.) "Big Chief Transparent Prophylactics Sold For The Prevention of Disease Only * * * H. L. Blake Co., Inc. * * * Hot Springs, Arkansas."

RESULTS OF INVESTIGATION: Examination showed that 1.1 percent of the units tested were defective in that they contained holes.

LIBELED: 11–4–63, W. Dist. Ark.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading; and 502(b)(1)—H. L. Blake Co., Inc., was not the manufacturer of the article and the label failed to bear a qualifying phrase such as "manufactured for and packed by * * *" or similar phrase which expressed the facts.

DISPOSITION: 12–26–63. Default—destruction.

8215. Rubber prophylactics. (F.D.C. No. 49358. S. No. 41–371 X.)

QUANTITY: 12 cases, each containing 20 ctns., each of which contained 12 sleeves, each sleeve containing 4 3-unit boxes, at New York, N.Y.

SHIPPED: 6–19–63, from Akron, Ohio, by Killashun Sales Div., The Akwell Corp.

LABEL IN PART: "Prime Prophylactics With SK–70 * * * Mfd. By The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that 0.8 percent of the units examined were defective in that they contained holes.

LIBELED: 10–14–63, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements "Assists in Protecting Health Through The Prevention Of Venereal Disease And Of The Reinfection Of The Female With Trichomonas" and "Sold For The Prevention of Disease Only" were false and misleading.

DISPOSITION: 12–12–63. Default—destruction.

8216. Rubber prophylactics. (F.D.C. No. 49517. S. No. 12–479 X.)

QUANTITY: 440 ctns., each containing 12 boxes, each box containing 4 3-unit pkgs., at Chicago, Ill.

SHIPPED: 7–24–63, from Memphis, Tenn., by National Hygienic Corp.

LABEL IN PART: (Pkg.) "Crest Naturac * * * Sold By Druggists Everywhere For Prevention of Disease * * * National Hygienic Products Corp. New York, N.Y."

RESULTS OF INVESTIGATION: Examination showed that 0.7 percent of the units examined were defective in that they contained holes.

LIBELED: 11–18–63, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold By Druggists Everywhere For Prevention of Disease" was false and misleading.

DISPOSITION: 1–13–64. Default—destruction.

DRUGS FOR VETERINARY USE

8217. Medicated feeds. (F.D.C. No. 46737. S. Nos. 27–896/7 T.)

QUANTITY: 14 50-lb. bags of *Cooper medicated layer ration* and 14 25-lb. bags of *Cooper Wormashot*, at Maryville, Mo.

SHIPPED: Between 12–28–60 and 1–5–61, from Humboldt, Nebr., by O. A. Cooper Co.

LABEL IN PART: (Bag) "Cooper F.P.I. Medicated Layer—No. 100 Complete Ration * * * Active Drug Ingredient Furazolidone 0.011% * * * Manufactured by The O. A. Cooper Company * * * Humboldt, Nebraska"; and "Cooper Wormashot Active Drug Ingredients: Phenothiazine 6.62% * * * The O. A. Cooper Co., Humboldt and Beatrice, Nebraska."

LIBELED: On or about 12–6–61, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the articles differed from that which they purported and were represented to possess, since the articles contained less than the declared amount of their active drug ingredients.

DISPOSITION: 9–19–62. Default—destruction.

8218. Medicated feed. (F.D.C. No. 50313. S. No. 85–733 A.)

QUANTITY: 50 100-lb. bags at Dornsife, Pa.

SHIPPED: 4–27–64, from Hagerstown, Md., by D. A. Stickell & Sons, Inc.

LABEL IN PART: (Tag) "Blue Ridge Feeds Medicated Poultry Booster Crumbles In chickens and turkeys. * * * Active Drug Ingredient Furazolidone * * * 0.022% * * * Manufactured by D. A. Stickell & Sons, Inc. Hagerstown, Maryland Feeding Directions * * * If grain is fed in addition to complete feed, increase proportion of medicated feed accordingly."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 57 percent of the declared amount of furazolidone.

LIBELED: 6–25–64, M. Dist. Pa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Furazolidone * * * 0.022%" was false and misleading; and 502(a)—the labeling contained false and misleading representations that the article, when used as directed, was adequate and effective as a treatment for fowl typhoid, paratyphoid, pullorum, blackhead, paracolon, air sac, synovitis, nonspecific enteritis (blue comb, mud fever), quail disease (ulcerative enteritis) in chickens and turkeys, infectious hepatitis in chickens, and hexamitiasis in turkeys.

DISPOSITION: 9–24–64. Consent—claimed by D. A. Stickell & Sons, Inc., and mixed with unmedicated feed for use as animal feed on claimant's farm.

8219. Diethylstilbestrol mix. (F.D.C. No. 50126. S. No. 4–613 A.)

QUANTITY: 50 50-lb. bags at Graceville, Fla.

SHIPPED: 2–11–64, from Denison, Tex., by Vit-A-Way, Inc.

LABEL IN PART: (Tag on bag) "Vit-A-Way 0.022% Diethylstilbestrol Mix In Vita-A-Way Feedlot Pro-Gro (B–A) (For Fattening Beef Cattle Only) Active Drug Ingredient Diethylstilbestrol 0.022% * * * Manufactured by Vit-A-Way, Inc. Fort Worth, Texas at Denison, Texas."

LIBELED: 5–14–64, N. Dist. Fla.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Diethylstilbestrol 0.022%" was false and misleading.

DISPOSITION: 11–19–64. Default—destruction.

8220. Fisher's Chick Starter Krumbles (medicated) feed. (F.D.C. No. 50551. S. No. 103–268 A.)

QUANTITY: 33 80-lb. bags at Portland, Oreg.

SHIPPED: 6–22–64, from Seattle, Wash., by Fisher Flouring Mills Co.

LABEL IN PART: (Bag) "Fisher's Chick Starter Krumbles (Medicated) As an aid in the development of active immunity to coccidiosis in chickens * * * Feed Continuously as the only ration. Active Drug Ingredient: Zoalene 0.0083% Caution * * * Ingredients * * * Procaine Penicillin * * * Manufactured by Fisher Flour Mills Company * * * Seattle, Washington."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 134 percent of the amount of Zoalene declared on the label.

LIBELED: 9–1–64, Dist. Oreg.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Zoalene 0.0083%" was false and misleading.

DISPOSITION: 9–25–64. Consent—claimed by Fisher Flouring Mills Co. and destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

8221. Powerin with Potentine tablets. (F.D.C. No. 47133. S. Nos. 48–444/7 T.)

QUANTITY: 29 180-tablet btls. and 88 60-tablet btls. at San Francisco, Calif.

SHIPPED: Between 6–6–61 and 8–16–61, from Yonkers, N.Y., by American Dietaids Co., Inc.

LABEL IN PART: (Btl.) "Man's Formula [or "Woman's Formula"] High Potency Powerin With Potentine* A Natural Activated High Potency Formula * * * U.S. Nutrition Products Co. Yonkers, N.Y., Dist. Each 3 tablets contain natural * * * in a base of *Potentine Brand Special Matte Concentrate Dosage: For a quick lift * * * As an iron deficiency tonic and for the prevention of vitamin and mineral deficiencies of essential factors present."

ACCOMPANYING LABELING: Window poster entitled "Sensational South American Plant Brings New Amazing Pep and 'Life' Within 15 Minutes."

RESULTS OF INVESTIGATION: Examination showed that the articles contained per tablet (Man's Formula) approximately 0.11 grams caffeine and (Woman's Formula) approximately 0.14 grams caffeine.

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*See also Nos. 8181, 8185, 8186, 8192, 8194–8198, 8200–8216, 8218–8220.

LIBELED: 2–20–62, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective to promote power; for a quick lift; as an iron deficiency tonic; for pep and "life"; to cause a work-tired, played-out body to get back its normal bounce in one quarter hour; and to feel like a brand new person because the articles furnished a new surge of energy; that the articles' base of maté concentrate was of sensational significance as a source of power; and that nutritional requirements of men and women were different from those of adults, generally.

DISPOSITION: Subsequent to the seizure, American Dietaids Co., Inc., claimant, filed an answer to the libel and also filed a motion to transfer the action to the District of New Jersey and, pursuant to stipulation between the parties, the case was transferred to the District of New Jersey. Subsequently, the Government served interrogatories upon the claimant. On 2–22–63, claimant filed answers to the Government's interrogatories. Thereafter, the claimant advised that it desired to abandon the articles and consent to their destruction. On 9–1–64, a decree of condemnation and destruction was entered.

8222. Perrigo cold capsules. (F.D.C. No. 50333. S. No. 49–061 A.)

QUANTITY: 80 ctns., each containing 12 10-capsule pkgs., at Allegan, Mich.

SHIPPED: 4–27–64, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Pkg.) "Perrigo Continuous Action Time Caps * * * One capsule in the morning and one capsule in the evening provide continuous 24-hour relief from the nasal congestion of common colds and hay fever. * * * dry up the watering of the eyes and running nose * * * reduce swelling in the tissues of the nose and to help drain nasal passages * * * counteract excessive sneezing and excessive nasal discharge * * * Each Capsule Contains: Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Scopolamine Hydrobromide 0.014 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Phenylpropanolamine Hydrochloride 50 Mgm. Chlorpheniramine Maleate 1 Mgm. Pheniramine Maleate 12.5 Mgm. Warning: Not to be used by * * * Caution Do not exceed * * * L. Perrigo Company, Allegan, Michigan, Distributors."

LIBELED: 7–9–64, W. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that a single *Perrigo Time capsule* containing the amounts of ingredients declared in the label would provide 12 hours of continuous relief of excessive sneezing and nasal discharge, running nose, watering of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 8–6–64. Default—destruction.

8223. Reliable cold capsules. (F.D.C. No. 50335. S. Nos. 6–907 A, 9–970 A.)

QUANTITY: 7,132 10-capsule pkgs. at Washington, D.C.

SHIPPED: 2–27–64, from New York, N.Y., by R–L Laboratories, Inc.

LABEL IN PART: (Pkg.) "Reliable Contained Action Cold Capsules 10 sustained action capsules * * * One Cold Capsule gives up to 12 hours relief * * * from sneezing, weeping, itching eyes and stuffed up nose * * * continuous relief from weeping eyes, nasal congestion, running nose, and excessive sneezing * * * Dosage: 1 capsule in the morning and 1 capsule at bedtime. Warn-

ing * * * Formula: Each Cold Capsule contains: Belladonna Alkaloidal Salts, Total 0.16 mgm. Atropine Sulfate 0.024 mgm. Hyoscyamine Sulfate 0.122 mgm. Scopolamine Hydrobromide 0.014 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. * * * Caution * * * Distributed by R–L Laboratories, Inc., New York, N.Y."

LIBELED: 7–7–64, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling of the article, namely, the package label, contained false and misleading representations that a single *Reliable cold capsule* containing the amounts of the ingredients declared in its label would provide 12 hours of continuous relief from excessive sneezing and nasal discharge, running nose, watering and itching of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 8–20–64. Default—delivered to the Food and Drug Administration.

8224. **Longac cold capsules.** (F.D.C. No. 50338. S. No. 6–640 A.)

QUANTITY: 122 cases containing 120 10-capsule pkgs. each, and 47 10-capsule pkgs., at Washington, D.C.

SHIPPED: 11–21–63, from New York, N.Y., by Doalbert Printing Co., Inc.

LABEL IN PART: (Pkg.) "Longac Up To 12 Hours Relief With One Capsule 10 sustained release capsules * * * Each capsule contains: Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Scopolamine Hydrobromide 0.014 Mgm. Phenylpropanolamine Hydrochloride 50 Mgm. Chlorpheniramine Maleate 1 Mgm. Pheniramine Maleate 12.5 Mgm. Prepared Expressly for Kent Pharmacal Co. Wilmington, Del. Washington, D.C."

LIBELED: 7–2–64, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that a single *Longac cold capsule* containing the amounts of the ingredients declared in the label would provide 12 hours of continuous relief of excessive sneezing and nasal discharge, running nose, watering and itching of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 9–8–64. Default—delivered to the Food and Drug Administration.

8225. **Impact cold capsules.** (F.D.C. No. 50425. S. Nos. 19–506/8 A.)

QUANTITY: 79 12-capsule pkgs., 111 30-capsule btls., and 19 30-capsule btls. (coded "31356"), at Rochester, N.Y.

SHIPPED: Between 4–12–63 and 10–31–63, from West New York, N.J., and St. Louis, Mo.

LABEL IN PART: (Pkgs. and 111-btl. lot) "Impact * * * Approved Pharmaceutical Corp. Syracuse * * * New York * * * Each Capsule Contains: Belladonna Alkaloids 0.16 Mgm. * * * Phenylpropanolamine Hydrochloride 50.0 Mgm. Chlorpheniramine Maleate 1.0 Mgm. Pheniramine Maleate 12.5 Mgm." and (19-btl. lot coded "31356") "Impact * * * Approved Pharmaceutical Corp. Syracuse Distributors New York * * * Each Capsule Contains: belladonna alkaloids: * * * total 0.25 mg.; phenylpropanolamine hydrochloride 50.0 mg.; prophenpyridamine maleate 25 mg. Warning."

RESULTS OF INVESTIGATION: The article had been shipped in bulk to Approved Pharmaceutical Corp., Syracuse, N.Y., which firm repacked and labeled the article as above and, thereafter, delivered it to a dealer in Rochester, N.Y.

LIBELED: 8–14–64, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained statements which represented and suggested that a single *Impact cold capsule* containing the amounts of ingredients declared in the labels would provide 12 hours of continuous relief of excessive nasal discharge, swelling of the nasal tissue, running nose and watering of the eyes, and stuffy, congested feeling caused by head colds, sinus, and hay fever (79-package lot), and congestion due to head colds, hay fever, and sinus (111- and 19-bottle lots), which statements were false and misleading, since the article was not adequate and effective for such purposes when taken as directed in the labeling.

DISPOSITION: 10–8–64. Default—destruction.

8226. Dietary food products. (F.D.C. No. 49376. S. Nos. 51–649/52 X.)

QUANTITY: 24 cases, each containing 36 100-capsule btls. of *Watkins Multi-Vitamins With Minerals For Children capsules*, 89 cases, each containing 36 100-tablet btls. of *Watkins Multi-Vitamins With Minerals chewable tablets*, 80 cases, each containing 36 100-capsule btls. of *Watkins Multi-Vitamins With Minerals capsules*, 19 cases, each containing 36 100-capsule btls. of *Watkins Special Geriatric Formula Multi-Vitamins With Minerals capsules*, at Seattle, Wash., in possession of Watkins Products, Inc.

SHIPPED: Prior to 8–15–63, from Winona, Minn., by Watkins Products, Inc.

LABEL IN PART: (Btl.) "Watkins 100 Dietary Food Capsules Multi-Vitamins With Minerals For Children 3 to 12 10 Minerals and 11 Vitamins All In One Capsule * * * Distributed by Watkins Products, Inc. Winona, Minnesota," "Watkins Multi-Vitamins With Minerals Chewable Tablets 100 Dietary Food Tablets For Ages 2 to 12 Years * * * Watkins Products, Inc. Winona, Minnesota," "Watkins 100 Dietary Food Capsules Multi-Vitamins With Minerals 10 Minerals and 11 Vitamins All In One Capsule * * *Distributed by Watkins Products, Inc. Winona, Minnesota," and "Watkins 100 Dietary Food Capsules Special Geriatric Formula Multi-Vitamins with Minerals 13 Vitamins – 9 Minerals Plus Whole Dried Liver, Rutin, Betaine, Choline and Methionine. All in One Capsule * * * Distributed by Watkins Products, Inc. Winona, Minn."

ACCOMPANYING LABELING: Leaflets reading in part "Vitamin–A (Palmitate) Guardian of your eyes."

RESULTS OF INVESTIGATION: The accompanying labeling had been prepared and mimeographed on order of the dealer for the purpose of promoting sales of the articles.

LIBELED: 10–2–63, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that all the articles were adequate and effective as a treatment and preventive of kidney stones, liver disease, gall-bladder disturbances, skin disorders, insanity, enlarged heart, varicose veins, rheumatic fever, heart disease, cerebral palsy, sterility, retarded growth, mental disorders, anemia, hay fever and other allergies; and that the *Watkins Multi-Vitamins With Minerals capsules* (80-case lot) were adequate and effective as a treatment and preventive of rundown conditions,

listless conditions, feeling of being "half-alive," and lack of energy and pep; and that the *Watkins Special Geriatric Formula Multi-Vitamins With Minerals capsules* were adequate and effective as a treatment and preventive of tiredness and lack of vigor.

DISPOSITION: 7–29–64. Consent—claimed by Watkins Products, Inc., formerly known as the J. R. Watkins Co., of Wilmington, Del., and Winona, Minn. The consent decree of condemnation provided for the salvaging of those of the seized articles containing .10 mg. or less folic acid per capsule, that such salvaging be accomplished by (a) destroying all of the above leaflets in the claimant's possession beginning with the words "Vitamin – A (Palmitate) Guardian of your eyes" and giving written instructions to all persons who received such leaflets from the claimant that the leaflets were not to be used in connection with the sale or distribution of the articles; (b) removing from the articles any and all labels, cartons, inserts or writings of any kind referring to rundown condition, listless condition, feeling of being "half-alive," lack of energy and pep, tiredness, and lack of vigor; and (c) relabeling said articles using only labels, cartons, containers, inserts or writings approved by the Secretary of Department of Health, Education, and Welfare, or his authorized representative; and (d) retaining all labels, cartons, or other writings presently on or in any containers of the articles and making disposition of the same as reasonably required by a duly authorized representative of the Secretary of the above Department.

Pursuant to the consent decree, the *Watkins Multi-Vitamins with Minerals chewable tablets* were returned to the claimant's Oakland, Calif., plant for relabeling, and the other articles were destroyed.

8227. Dexettes tablets. (F.D.C. No. 50442. S. No. 52–085 A.)

QUANTITY: 480 21-tablet btls. at Lima, Ohio.

SHIPPED: 7–1–64, from Hollywood, Fla., by Pharmex, Inc.

LABEL IN PART: (Btl.) "Super Dexettes Anti-Tussive Decongestant Caution—May cause loss of appetite Each tablet contains: Phenylpropanolamine Hydrochloride 25 mg. * * * Adult Dose: * * * Distributed by C. M. Hunter Drug Co., Lima, Ohio."

LIBELED: 8–10–64, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the label statements "Caution—May cause loss of appetite" and "Adult Dose: One tablet ½ hour before each meal," were false and misleading in that they represented and suggested that use of the article, as directed in its labeling, was effective to suppress the appetite, whereas the article was not effective for such purpose.

DISPOSITION: 9–24–64. Default—destruction.

8228. Trimeze capsules. (F.D.C. No. 50571. S. No. 65–061 A.)

QUANTITY: 3 ctns., each containing 12 30-capsule boxes, and 1 ½ ctn. containing 3 60-capsule boxes, at Los Angeles, Calif.

SHIPPED: Between 2–6–64 and 8–4–64, from Philadelphia, Pa.

LABEL IN PART: (Box) "Trimeze a reducing aid Directions—One Capsule, Once Daily * * * Each capsule contains as active ingredients: Phenylpropanolamine Hydrochloride 75 mg. * * * Caution * * * Executive Products, Los Angeles, California Makes a low calorie diet easy!"

ACCOMPANYING LABELING: "Eat what you like but . . ."

RESULTS OF INVESTIGATION: The article was shipped as described above in bulk

lots on order of Executive Products, Woodland Hills, Calif., to Riders, Ltd., Saugus, Calif., where the article was repacked into boxes as described above, and subsequently reshipped to the dealer.

LIBELED: 9–9–64, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling, including the name of the article, contained false and misleading representations that the article was adequate and effective as an aid for reducing; that you might eat what you like but lose weight the comfortable way; that the article would supply extra pep and energy and assist in relieving the low-down, depressed feeling you usually have on a diet; and that you would feel better all day the easy way.

DISPOSITION: 10–6–64. Default—destruction.

8229. **X-Drin tablets.** (F.D.C. No. 50401. S. No. 12–641 A.)

QUANTITY: 7,800 21-tablet btls. and 1,764 90-tablet btls., at Pawtucket, R.I.

SHIPPED: 2–24–64, from Syracuse, N.Y., by Approved Pharmaceutical Corp.

LABEL IN PART: (Btl.) "X-drin For Appetite Suppression To Aid Weight Reduction Distributed by Halls Albany Corp. Albany, New York Each tablet contains Phenylpropanolamine Hydrochloride 25 mg. Dosage: One tablet three times daily * * * Caution."

ACCOMPANYING LABELING: Package insert entitled "Safe & Sane Reducing Plan"; and display carton entitled "Reduce Scientifically X-drin Tablets Cuts Desire For Food No Hunger Pains Safe Prescription No Longer Required Appetite Depressant Tablets."

LIBELED: 7–29–64, Dist. R.I.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for appetite suppression; to aid weight reduction; control appetite and yet maintain energy and a sense of well-being; and that results were guaranteed.

DISPOSITION: 10–1–64. Default—destruction.

8230. **Vita Trim diet wafers.** (F.D.C. No. 50115. S. No. 51–388 A.)

QUANTITY: 650 cases, each containing 12 60-wafer boxes, at Detroit, Mich.

SHIPPED: 7–2–62, from Naperville, Ill., by Savoy Drug & Chemical Co.

LABEL IN PART: (Box) "Vita Trim Plan The Tasty Plan To Lose Weight For Men and Women * * * Contents: 60 Wafers Each 4 Wafers contains: * * * 75 mg phenylpropanolamine HCl * * * Directions; * * * Each wafer contains 458 mgs. of Protein and 10 Calories * * * 5 Delicious Flavor Rolls * * * Food Supplement, Inc., Detroit, Mich."

ACCOMPANYING LABELING: Package insert reading in part "Vita Trim and The Vita-Trim Reducing Plan Simpler–Faster–Safer"; and display carton reading in part "The Tasty Plan To Lose Weight Vita-Trim Plan * * * causing you to eat less and automatically lose weight."

LIBELED: 5–25–64, E. Dist. Mich.; libel amended 7–2–64.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective in curbing the appetite and causing weight loss.

DISPOSITION: 9–22–64. Default—destruction.

8231. **High-frequency device.** (F.D.C. No. 50312. S. No. 88–912 A.)

QUANTITY: 1 device at Advance, Mo.

SHIPPED: In 1956, from Austria, by Mrs. Sara Hunterberger.

LABEL IN PART: "Helios."

ACCOMPANYING LABELING: Books entitled "Werde und bleibe gesund! Gesundheit Heilung und Genesung durch Hochfrequenz," "Werde und bleibe gesund durch Hochfrequenz–Bestrahlung," and "Die Hochfrequenz als Verjungungsmittel."

RESULTS OF INVESTIGATION: The article was a high-frequency violet ray generator housed in a rigid carrying case about the size of a brief case, accompanied by variously shaped glass electrodes used for applying the current to the body.

LIBELED: 10–13–64, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of neuralgia, pains in the back of the head and neck, stomach pains, pains, in the chest, rheumatism, nervous conditions, and diseases of the nerves, epilepsy, migraine headaches, mumps, catarrh, hemorrhoids, diabetes, grippe, tuberculosis and multiple sclerosis.

DISPOSITION: 11–19–64. Default—destruction.

8232. Brassiere device. (F.D.C. No. 50403. S. No. 62–094 A.)

QUANTITY: 33 devices at Los Angeles, Calif., in possession of Ann Kaufman's Specialty Shop.

SHIPPED: 5–29–64, from Shellebelle, Belgium.

LABEL IN PART: "Amazing Bra Made in Belgium."

ACCOMPANYING LABELING: Placards reading in part "Adds Inches or Minimizes Instantly," "Add Inches Instantly or Minimize Larger Bust," and "Non Maternity Custom Bra Adds Inches Instantly & Permanently"; reprint of photograph which appeared in Bazaar magazine and reprint from Los Angeles Times, headed "Its New . . ."; a card, 2½x3 inches, reading in part "The Amazing! Bra"; framed testimonials and photographs; and mimeograph sheet headed "Ann Kaufman's Specialty Shop * * * It's New."

RESULTS OF INVESTIGATION: Examination showed the article of device to be a lined, lace brassiere with semi-detachable cups having several hooks at various points along the outer edge of the cups for placing the cups in various positions by attaching the hooks to the desired position on the outer edge of the brassiere.

The accompanying labeling had been designed by the dealer for the promotion of the article.

LIBELED: 7–23–64, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective to increase or decrease the size of the bust; encourage natural development; improve health and posture; prevent any possibility of sagging; cause instant firming, tightening and revitalizing of the pectoral muscles; and stimulate healthful blood circulation.

DISPOSITION: 9–10–64. Default—destruction.

8233. Contour Whirlpool device and accessories. (F.D.C. No. 49965. S. No. 19–323 A.)

QUANTITY: 1 unlabeled ctn. containing 1 unlabeled device, 1 unlabeled plastic carrying case, and 1 individually ctnd. jar of cream, at Rochester, N.Y.

SHIPPED: 11–1–63, from Fort Lauderdale, Fla., by Brigitte Products, Inc.

LABEL IN PART: (Jar) "Creme De Jouvence."

ACCOMPANYING LABELING: Brochure entitled "Perfect Breasts" reading in part "Contour Whirlpool is the remarkable new method for firming and developing your breasts"; picture card illustrating the "Contour Whirlpool"; letter on Brigitte Products, Inc., letterhead, beginning "Dear Madam:"; folder entitled "So Happy to Hear About Baby"; card reading in part "I am quite certain that you, like many other mothers, are anxious to restore the firmness and beauty of your bosom as quickly as possible. You can do this safely and naturally with 'Contour Whirlpool'."; and newspaper advertisement which appeared in the Miami Herald on October 27, 1963, reading in part "Let Brigitte Help With Your Bosom Problem!".

RESULTS OF INVESTIGATION: Examination indicated that the article consisted of a cup-shaped plastic covering to be connected to the water faucet by means of a rubber tubing; and that when the device was cupped over the breast and the water turned on, the breast was sprayed with water.

LIBELED: 5–6–64, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective to develop and restore firmness to the breasts, particularly after pregnancy; to produce good muscle toning and to quickly replace flabbiness with new erectness in the breasts; regenerate skin; stimulate lymphatic circulation; and arouse sleeping muscles in heavy breasts; and that use of the device and cream, as directed, would result in firm, strong, beautiful, perfect breasts.

DISPOSITION: 9–9–64. Default—delivered to the Food and Drug Administration.

8234. Nev-R-Age face and figure exerciser. (F.D.C. No. 50153. S. Nos. 60–926 A, 61–550 A.)

QUANTITY: 3 devices, at Phoenix, Ariz., in possession of A–M Products Corp.

SHIPPED: 4–10–64, from Los Angeles, Calif.

LABEL IN PART: "Mary Lee's Nev–R–Age Facial Exerciser * * * A–M Products Corp. * * * Phoenix, Ariz."

ACCOMPANYING LABELING: Pamphlets entitled "Mary Lee's Nev–R–Age Dear Friend"; leaflets entitled "Mary Lee's Nev–R–Age Face and Figure Exerciser Supplemental Instructions" and "Look more youthful."

RESULTS OF INVESTIGATION: The device consisted of a motor-driven vacuum pump in a carrying case, with attachments consisting of a flexible latex hose with plastic suction cups. When the suction cups were placed on various parts of the body, varying vacuum intensities caused the skin beneath the suction cups to be stretched and released. The accompanying labeling was held by the dealer for use in the promotion of the device.

LIBELED: 5–27–64, Dist. Ariz.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to firm, tone, and contour the figure; eliminate wrinkles from chin and lips; remove impurities beneath the skin; exercise the entire body; eliminate sagging of upper arms; increase circulation to build tissue, build muscles, muscular tone and firmness of face and neck, and for spot reducing and relaxation.

DISPOSITION: 7–22–64. Default—destruction.

8235. **Figurelite device.** (F.D.C. No. 50421. S. No. 25–939 A.)

QUANTITY: 23 devices, in cases, at Chicago, Ill.

SHIPPED: 7–6–64, from Dallas, Tex., by Figurelite Co.

LABEL IN PART: (Device) "Figurelite."

ACCOMPANYING LABELING: Booklets entitled "Bioelectronics Figure Care System Sales Presentation Manual and Additional Sales Information"; leaflet containing photographs of people "before and after 60 days"; and leaflet entitled "Figurelite Your Exercise Program."

RESULTS OF INVESTIGATION: The article was an electronic muscle stimulator housed in a black attache-type carrying case with white metal fittings. A control panel had four control knobs and three toggle switches. Attached to an electrical pulse generator was a cord for plugging the device into an electrical outlet, and a set of pad electrodes for applying electrical impulses to the body. In use, the device might cause involuntary contractions and relaxation of muscles.

LIBELED: 8–4–64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for reducing body weight with ease; reducing the size of sagging and untoned muscles; causing immediate measurable size loss in hips, waist, legs and other parts of the body of as much as one inch in 30 minutes; to trim size without exhausting effects of physical exercise; for correcting body posture, and the correction of remediable postural defects; spot-reducing and for all-over body tone; complete figure control and body beautification; tightening and toning sagging and untoned muscles; deeper and more beneficial muscle exercise; bringing extra nourishment to your face; preventing degenerative disease and to slow down the physical deterioration that accompanies aging; to make you look younger and stay younger; for amazing results on sagging face muscles and to make face-lifting easier; that the device was a miracle of modern science, the use of which provided a healthful new method of reducing which eliminated strict dieting and other outdated methods; that about a half dozen treatments would do the trick of restorative treatment for older women, and that use of the device would reduce your metabolism and result in effortless exercise just as active and vigorous as working out in a gymnasium; and that using the device once a week would keep your inches where you want them and correct health hazards that haunt cooped-up, work-drowned United States business men.

DISPOSITION: On 8–25–64, the Figurelite Co. filed Motions for Destruction of Certain Promotional Material and for Dismissal of Libel of Information and a Brief in Support of these Motions. These Motions were dismissed for failure to name an attorney having offices within the jurisdiction of the court. On 11–5–64, a default decree of condemnation was entered directing that the article be delivered to the Food and Drug Administration.

8236. **Plastic garments.** (F.D.C. No. 49929. S. No. 62–043 A.)

QUANTITY: 300 unlabeled plastic garments at Las Vegas, Nev., in possession of Tray-Lynn of Las Vegas (Eileen Glidewell and Barbara Castle).

SHIPPED: 11–15–63, from Los Angeles, Calif.

ACCOMPANYING LABELING: Card entitled "Tray-Lynn of Las Vegas," and leaflet containing order blank entitled "Tray-Lynn of Las Vegas."

RESULTS OF INVESTIGATION: In the course of the dealer's business, the card and leaflet were packed with each garment before mailing to the customer. Examination showed that the articles consisted of translucent plastic undergarments in the form of chemise, knee-length pants, and short pants. In use the garments were supposed to be worn over an inner cotton or other fabric garment intended to absorb perspiration induced by body heat.

LIBELED: 4–3–64, Dist. Nev.

CHARGE: 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective as a treatment for slimming and controlling the figure, melting away fatty tissue, reducing body weight, losing unwanted inches and for reducing and slenderizing only where one desired.

DISPOSITION: 6–3–64. Default—destruction.

8237. **Dr. Scholl's Electric Foot Massager devices.** (F.D.C. No. 50277. S. Nos. 62–143/4 A.)

QUANTITY: 102 single-unit devices and 204 dual-unit devices, at Chicago, Ill.

SHIPPED: 5–15–64, from Los Angeles, Calif., by Scholl Manufacturing Co., Inc.

LABEL IN PART: (Top of device) "Dr. Scholl's Electric Foot Massager," (underside) "* * * The Scholl Mfg. Co. Inc. Chicago, Ill."

ACCOMPANYING LABELING: Dr. Scholl's Catalog #62 and Dr. Scholl's Catalog #159; leaflets entitled "New! * * * Dr. Scholl's Electric Foot Massager"; folders entitled "How to use Dr. Scholl's Electric Foot Massager" (directions for using single unit); and folders entitled "How to use Dr. Scholl's Electric Foot Massager" (directions for using dual unit).

LIBELED: 6–2–64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that they were adequate and effective as a treatment for strengthening foot muscles; temporary numbness in feet due to fatigue; numbness in feet and toes and pain in the metatarsal area; simple neuralgic pains in the feet; muscular cramps of the toes and the ball of the foot; arthritic feet; neuritis in legs; weak arches; poor circulation; and to improve circulation in any part of the body; ease muscular pain at the small of the back; help strengthen weak muscles of the foot arch; help tone up the muscles and superficial nerves; and to provide healthful, stimulating action which gives much the same benefit as hand massage.

DISPOSITION: 7–22–64. Consent—claimed by Scholl Manufacturing Co., Inc., Chicago, Ill., and relabeled.

8238. **Suncap Ozone Generators.** (F.D.C. No. 50134. S. Nos. 96–696 A, 96–699 A.)

QUANTITY: 7 devices at San Francisco, Calif.

SHIPPED: Between 1–1–63 and 3–12–64, from Philadelphia, Pa., by Suncap Systems, Inc.

LABEL IN PART: "Suncap Systems * * * Electronic Purifier * * * Suncap Systems, Inc. Phila. 39, Pa."

ACCOMPANYING LABELING: Cover letters entitled "New! Suncap Systems Electronic Purifier," with a sheet attached entitled "How Is Ozone Generated?"; and testimonial letters headed "P.O. Box 388, Lodi, Calif."

RESULTS OF INVESTIGATION: The articles were electronic ozone generators in two different models, housed in different, small table-model cabinets, each having an "off-on" switch on the front panel and a connector for plugging into house current. In use the devices emitted ozone into the air.

LIBELED: 5–15–64, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for sterilization of air; sinus; hay fever; asthma; tonsilitis; sore throat; colds; headache; stomach ache; earache; toothache; indigestion; fever; la grippe; and pneumonia.

DISPOSITION: 10–6–64. Consent—claimed by Suncap Distributing Co., San Francisco, Calif., to be brought into compliance with the law.

8239. **Sun-Lite-Aire device.** (F.D.C. No. 44418. S. No. 2–161 R.)

QUANTITY: 3 *Sun-Lite-Aire devices* at Statesville, N.C.

SHIPPED: 2–10–60 and 2–12–60, from Chicago, Ill., by Sampson Chemical & Pigment Corp.

LABEL IN PART: "Sampson Sun-Lite-Aire Ion Ray Air Purifier * * * Manufactured by Sampson Chemical & Pigment Corp. * * * Chicago, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "Sampson 'Sun-Lite-Aire' Purifier," and "Here's Good News for People Who Suffer From Hay Fever, Asthma, Sinus, Colds, and Dust Allergies."

RESULTS OF INVESTIGATION: Examination indicated that the article was a metal box-shaped device, 3″ x 3½″ x 10″ in size, enclosing a transformer. An ultraviolet lamp, extending from one end of the metal housing, was intended to be inserted within the return duct of the heating or air-conditioning unit of the house. The unit operated on ordinary house current.

LIBELED: 4–12–60, W. Dist, N.C.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for preventing poliomyelitis, tuberculosis, common cold, influenza, meningococcic infections, German measles, scarlet fever, measles, streptococcus throat, whooping cough, encephalitis, chicken pox, small pox, pneumonia, diphtheria, respiratory diseases, asthma, hay fever, and sinus.

DISPOSITION: On or about 6–16–60, Sampson Chemical & Pigment Corp. claimed the devices and the leaflets accompanying them and denied that they were misbranded. On 4–10–62, the Government served written interrogatories on the claimant. On 5–28–62, the claimant served answers to the interrogatories. On 12–3–62, the Government served supplemental written interrogatories on the claimant. On 1–2–63, the court issued an order that one device and a specimen of each piece of labeling involved be turned over to the Government for examination. On 1–21–63, the claimant moved to quash the Government's demand for answers to the supplemental written interrogatories. On 6–20–63, a consent decree of condemnation was filed which provided for the release of the article to the claimant for relabeling.

On 10–12–64, the court found that the conditions of the consent decree had not been performed, since the claimant failed to provide acceptable labeling to complete the reprocessing of the seized devices; and the court ordered the devices destroyed. On 10–16–64, the articles were destroyed.

8240. Broilitizer device. (F.D.C. No. 50328. S. No. 6–661 A.)

QUANTITY: 10 devices at Washington, D.C., in possession of Smith's, Inc.

SHIPPED: 6–11–64, from Beloit, Wis., by Robert L. Patrick Associates.

LABEL IN PART: (Device) "Smokeless Broilitizer Mfg. by Shoup Engineering Corp. East Troy, Wisc."; (ctn.) "Smokeless * * * Broilitizer From Robert L. Patrick Associates * * * To Smith's, Inc."

ACCOMPANYING LABELING: Booklet entitled "Description-Instuctions-Recipes Broilitizer"; leaflets entitled "Model No. 5 Broilitizer For Your Health's Sake" and "Cholesterol Conscious?"

RESULTS OF INVESTIGATION: Investigation indicated the article to consist of an alternating current, ribbon-type heating element similar to that used in toasters, housed in a pan the bottom of which was designed to hold water to keep drippings from burning. A grill was set just above the heating element, and the unit contained a loose-fitting, wire, basket-type cover.

The leaflet entitled "Cholesterol Conscious" had been printed on order of the dealer, and the other accompanying labeling had been supplied by the shipper.

LIBELED: 7–1–64, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that use of the article removed saturated fats from the diet, thereby eliminating cholesterol, overweight, gallbladder trouble, and diabetes; restoring vigor, strength and energy; and insuring a longer, more healthful life.

DISPOSITION: 8–20–64. Consent—claimed by Smith's, Inc., for relabeling.

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[1] (8195, 8221, 8235, 8239) Seizure contested.

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[1] (8195, 8221, 8235, 8239) Seizure contested.
[2] (8198) Seizure contested. Contains opinion of the court.

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[1] (8195, 8221, 8235, 8239) Seizure contested.
[2] (8198) Seizure contested. Contains opinion of the court.

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[1] (8195, 8221, 8235, 8239) Seizure contested.

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